Impact of a Standardized Asthma Education Program for Children Ages 8-12 years old with Moderate to Severe Persistent Asthma on Health Outcomes: A Pilot Study

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ABSTRACT

Impact of a Standardized Asthma Education Program for Children Ages 8-12 years old with Moderate to Severe Persistent Asthma on Health Outcomes: A Pilot Study

Felesia Bowen

Asthma is one of the most common chronic diseases of childhood causing significant physical, emotional and financial burden. The purpose of this study was to pilot recruitment strategies, instruments and experimental protocols to determine the feasibility of conducting a larger randomized control trial (RCT) and to evaluate educational, behavioral and physiological health outcomes for children ages 8 to 12 years of age with moderate to severe persistent asthma. The 30 subjects in this pilot were recruited at the time of hospital and emergency department admissions, randomized to standard care or care plus the Open Airways program, and assessed at three time points with a knowledge test, quality of life and disease control questionnaires, and spirometry to determine measures of large and small airway function. Subjects in the intervention group demonstrated significant and sustained improvement in asthma knowledge and their quality of life trended toward significance in the emotional subdomain. There was improvement over time within both groups on all health outcome measures except spirometry but repeated measures analysis of variance showed no
significant difference between groups for measurable lung function, quality of life or level of asthma control. Both groups experienced high levels of tobacco exposure with and without other environmental pollutants. The pilot study validated methods applicable to a larger RCT and suggested protocol revisions in intervention content, monitoring of control group, and timing of data collection. This study is innovative in that it focused on recruiting and intervening with urban children who have moderate to severe persistent asthma and it measured lung function and quality of life as well in addition to knowledge relative to a standardized educational intervention developed and widely used for children with milder disease. Incorporating the protocol refinements suggested in a larger RTC can potentially establish empirical evidence for an intervention tailored to the needs of children who are more seriously impacted by asthma and harder to reach for delivery of effective interventions.
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Dedication

This is dedicated to all of the children with asthma. It is my desire that one day you will be able to breathe easily and run and play without any discomfort.
CHAPTER ONE

Introduction

Asthma is the most common chronic disease in children and adolescents (Quinn et al, 2006). Over the past decade, morbidity and mortality associated with asthma have steadily increased in the United States. According to the Center for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), in 1995 nearly 14.8 million Americans had been diagnosed with asthma. In 2008 that number had increased to a staggering 23.4 million Americans (National Center for Health Statistics, 2008. tables 3, 4). Over the past 13 years, the incidence of asthma in children has increased from 5 million children under the age of 18 to 7 million (National Center for Health Statistics, 2008, table 1). Asthma exacerbation is the number one cause of school absenteeism (Quinn et al, 2006; Wong & Baker, 2003; NHBLI, 1997; AAAAI, 1999). According to the NCHCS (2005), in 2002 school children between the ages of 5 and 17 missed 14.7 million days of school. This is an increase of approximately 4.7 million more school absences in 4 years. Children residing in urban areas have the highest prevalence of asthma and the highest asthma associated hospitalization rates (Ortega, et al, 2002; Aligne et al, 2000; Wallace et al, 2003; National Health Interview Survey, 2004; Quinn et al, 2006). Studies from major metropolitan areas revealed that poor children from non-white neighborhoods have a 2- to 10-fold higher rate of hospitalization and death when compared to adjacent
poor neighborhoods and national norms (Liao et al, 2006; Jones & Clement, 2003; Frederico & Liu, 2003).

Background and Significance

Asthma is a life threatening, chronic pulmonary inflammatory disease characterized clinically by periods of exacerbation and resolution. Clinical manifestations of exacerbation may include any combination of the following: recurrent wheezing, shortness of breath, non-productive cough, chest tightness and chest congestion (Kilburn, 1998; Turcios, 2000; & Wong & Baker, 2003).

The exact cause of asthma is uncertain, yet it is known that asthma is an expression of both genetic predisposition and environmental factors (Turcios, 2000; Reed, 2006). Research suggests that asthma acts on a cellular level and is the result of interactions between chemical mediators and neural pathways that lead to an airway inflammatory response. The result of this chronic inflammatory process is airway hyper responsiveness. This chronic inflammation causes thickening of the basal cell membrane and smooth muscle hyperplasia and hypertrophy. This process can result in permanent damage to the bronchial epithelial cells known as airway remodeling (Bisgaard, 1997). Airway remodeling causes severe damage of the airway epithelium with areas of denudation and areas of regeneration, and the ratio of normal ciliated cells to goblet cells is decreased. This results in generalized edema with severe submucosal inflammation. This inflammation
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is characterized by the presence of eosinophils, lymphocytes, plasma cells, and degranulated mast cells. These changes are irreversible and occur early in the course of the disease (Bisgaard, 1997; Sveum, 2005; NHLBI, 2007). According to Bisgaard (1997), adolescents and adults with a history of uncontrolled asthma during childhood exhibited decreased lung function even though they had not reported symptoms in recent years. Therefore, it stands to reason that early and appropriate intervention that results in optimal disease management will help reduce the severity of airway remodeling in later years.

Several studies suggest correlations between asthma and lower socioeconomic status, poor environmental conditions (indoor allergens, and pollutants, dust mites, cockroaches and other vermin), psychosocial problems (i.e. depression, anxiety and denial) severe disease, limited access to health care, race, and gender (Malveaux & Fletcher-Vincent, 1995; AAAAI, 1995; NHBLI, 2007; Turcios, 2000; Jones & Clement, 2003; Quinn et al, 2006). Despite improved diagnostic measures, treatment, and overall outcome, asthma morbidity and mortality remain disproportionately higher among Black children who live in inner-city areas (NAEPP, 2003 & Swartz; et al., 2005). Mortality rates associated with asthma for Black children are approximately five times higher than that of White children and Black children are three times more likely to die from asthma than their White counterparts (NHBLI, 2007).
In 1998, 16.3% of the U.S. population was uninsured, 13.1% lived below 100% of the U.S. poverty level and 31.1% lived below 200% of the U.S. poverty level (USDHHS, HRSA, 2000). The lack of medical care often results in increased emergency department (ED) use for regular health care. Halfon & Newacheck (1993) found that poor children with asthma had 40% fewer physician visits, yet were 40% more likely to be hospitalized. Treatment in the ED for asthma or any other chronic health problem does not allow for follow up and preventive care. These are more readily provided when the child sees a primary care provider or is managed by a specialist (pulmonologist or allergist) (Schatz et al, 2005). Reliance on crisis care greatly increases morbidity and mortality rates among minority children with asthma (Joseph et al, 1998). However, desperate parents know that when they bring their child to the ED in respiratory crisis, they will not be turned away due to their inability to pay for services.

In 2002, children with asthma accounted for five million physician visits and 484,000 hospitalizations (NCHCS, 2005) compared to nearly three million physician visits and 200,000 hospitalizations each year in previous years (Flores et al, 2002). The annual health care costs associated with pediatric asthma treatment is 3.2 billion dollars annually (American Lung Association, 2003). The indirect costs associated with missed days of work for parents are approximately 1 billion dollars annually (Flores, 2002).
Summary of Problem

Children who live in urban areas are more at risk for developing asthma than those who do not live in urban areas. Access barriers such as limited finances for medications and monitoring devices, and limited access to providers with expertise in pediatric asthma care compound these risks. Poorly managed or untreated asthma can result in increased morbidity, long-term lung dysfunction or death.

A limited understanding of asthma pathophysiology and medication indication by children and their parents may contribute to increased asthma morbidity (Homer et al, 1996). Asthma education is essential to successful self management of the disease (Turcios, 2000; NAEPP, 1997; Kumar et al, 2005; Swartz et al, 2005). Health education programs can reduce morbidity and decrease costs associated with pediatric asthma (Turcios, 2000; Kumar et al, 2005; NHLBI, 2007). Asthma education should be initiated at the time of diagnosis and it should be reinforced at every subsequent visit. Successful programs should include both verbal and written instruction as well as demonstration of devices (NAEPP, 2007).

Purpose/Aim

The purpose of this study is to determine if positive health outcomes (improved pulmonary function, improved quality of life, improved asthma knowledge and decreased symptom exacerbation) occur for children with moderate to severe persistent asthma that live in an urban environment and...
participate in the structured asthma education program Open Airways for Schools.

Research Question

What effect in terms of pulmonary function, quality of life, and symptom exacerbation, does the Open Airways Asthma Program versus usual provider asthma care have on health outcomes for children 8-12 years old who have moderate to severe asthma?

Hypothesis

$H_1$: Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the Open Airways Asthma education program will experience improved pulmonary function when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual provider asthma care.

$H_2$: Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the Open Airways Asthma education program will demonstrate improved asthma knowledge when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual provider asthma care.

$H_3$: Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the
Open Airways Asthma education program will report improved quality of life when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual asthma care.

\( H_4 \): Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the Open Airways Asthma education program will report less symptom exacerbation when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual provider asthma care.
### Concepts/Variables

Key concepts in this study include: asthma, pulmonary function, asthma knowledge, asthma education, quality of life, and symptom exacerbation.

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<th>Concept/Variable</th>
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<th>Operational Definition</th>
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<td>Asthma</td>
<td>Chronic airway inflammation with periods of bronchial edema, bronchial constriction, expiratory wheeze, nonproductive cough, nonspecific night cough, shortness of breath and retractions. Review of history, physical examination and an established diagnosis by a health care provider will define a subject as having asthma.</td>
<td>Review of the subject's history and an established diagnosis by a health care provider will define a subject as having asthma. Asthma severity will be determined by guidelines established by the National Heart Lung and Blood Institute.</td>
</tr>
<tr>
<td>Pulmonary Function:</td>
<td>The measure and degree of airway obstruction.</td>
<td>Forced expiratory volume in one second (FEV₁), and FEF₂₅-₇₅ as measured by spirometry. Administer a ten question asthma knowledge test pre and post intervention and 3 weeks post intervention.</td>
</tr>
<tr>
<td>Asthma Knowledge:</td>
<td>Information the subject possess regarding asthma pathophysiology, medications, and triggers.</td>
<td>For the experimental group: Presentation of Open Airways for Schools Asthma Education Program For the control group: Usual asthma care and information that is provided by the provider</td>
</tr>
<tr>
<td>Asthma education</td>
<td>Information that is presented to the subject according to NIH guidelines that will enable the subject to recognize and manage symptoms of asthma.</td>
<td>Completion of the Pediatric Quality of Life Questionnaire (PAQLQ) by the subject.</td>
</tr>
<tr>
<td>Quality of Life:</td>
<td>The subject's pleasure or displeasure with his current life situation now that he has asthma.</td>
<td>Completion of the Childhood Asthma Control Test (modified) with a cut score equal to or less than 19.</td>
</tr>
<tr>
<td>Symptom Exacerbation</td>
<td>The subject's perception of increased asthma symptoms and the need for increased controller medication use.</td>
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The Role of Education in Asthma

Failure to aggressively manage asthma is more likely to result in hospitalizations, emergency room visits, and increased work and school absenteeism (Watkins, 1999). NAEPP guidelines indicate that successful asthma management consists of four components: assessment and monitoring, patient education, trigger control, and pharmacologic therapy. While patient education may seem like a minor entity, however after assessment it is by far the most critical component of the management quad. Patients may have a correct diagnosis, endure extensive diagnostic evaluations to identify triggers and have the best medication prescribed. However, if they are not taught how to effectively manage the day to day symptoms of this chronic illness they may experience repeated exacerbations and negative sequela associated with chronic airway inflammation (Chapman et al, 2008).

The NAEPP has described minimal objectives for asthma education. However, various educational approaches exist. They vary in length, didactic content, and setting. Evaluation of asthma education programs differ in rigor and content. Evaluation may consist of physiologic and humanistic outcomes, economic outcomes, knowledge retention or a combination. The major short-term goal of any asthma education program is to motivate patients to enroll in and complete a recommended curriculum (Watkins, 1999). Controlled studies are needed to assess and evaluate asthma programs in terms of the
NAEPP asthma program goals and clinical outcomes such as improve pulmonary function. It is expected that by incorporating this particular program, children between the ages of 8 and 12 with moderate to severe persistent asthma who are at the highest risk of poor outcomes in terms of disease severity, environmental and psychosocial factors, will benefit from participation in an asthma education program. Open Airways for Schools is a standardized asthma education program for children ages 8 to 12 years of age. The program has been extensively tested in the literature and has been shown to increase asthma knowledge and self efficacy (American Lung Association, 2005).

Study Purpose and Significance

This study is important because it will demonstrate whether or not a structured asthma education program results in positive health outcomes in children with moderate to severe persistent asthma. Children with moderate to severe persistent asthma are at highest risk for poor health outcomes in terms of increased morbidity and mortality. They tend to consume more health care resources due to poorly controlled asthma and increased symptoms, thus increasing their personal burden and societal burden of asthma. This study hopes to demonstrate that participants will experience not only improved asthma knowledge, but improved pulmonary function, improved quality of life and decreased asthma symptoms.
CHAPTER TWO

Review of Literature

Introduction

There is a vast amount of literature regarding asthma and its various management components. This review of literature will examine the current state of the science as it pertains to research about asthma education and its effects on clinical outcomes as stated in the National Asthma Education and Prevention Program (NAEPP). Research was scrutinized to determine whether or not educational programs adhered to the NAEPP guidelines and if measurable clinical outcomes were a part of the study. PUBMED was used to search keywords: asthma education, clinical outcomes, pediatric asthma, and asthma action plan within the past ten years (1996-2006). The following search limits were set: English language, subject age 0-18 years, and publication date within the past ten years. Some older references were cross-referenced from articles that are more recent.

Background

To better understand the current recommendations for asthma diagnosis and management a brief history describing the development of the “gold standard” of asthma management is provided. Asthma has challenged the best practitioners as they have attempted to intervene on behalf of patients (Marketos & Ballas, 1982). In 1946, Curry defined asthma in terms of airway variability and in 1959; the first attempt at systematically defining
asthma was made (Fletcher et al, 1959). The American Thoracic Society modified the definition of asthma to include the hyper-responsiveness of the trachea and bronchi (American Thoracic Society, 1962). In the mid 1970's scientists discovered, that asthma was more a problem with airway smooth muscles (Woolcock, 2000). In the late 80's asthma was recognized as the most common disease of childhood (NIH, 1997) affecting approximately 4.8 million children (CDC, 1995). To address this health problem of epidemic proportion, in 1989 the National Heart Lung and Blood Institute (NHBLI) convened an expert panel of researchers and providers to approach the issue of diagnosis and management of asthma. This expert panel was tasked with the development of a guideline or protocol for the diagnosis and management of asthma based on the current science (NIH, 2007). Their work was entitled the Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma. The Expert Panel Report (EPR) contained four components for the effective management of asthma: 1. Use of objective measures to assess disease severity and measure pulmonary function. 2. Measures to avoid or minimize environmental factors that precipitate symptoms. 3. Recommendations for pharmacotherapy aimed at preventing exacerbations and reversing airway inflammation. 4. Patient education recommendations for the treatment of asthma.

An international group of asthma experts in conjunction with the NHLBI used the information from the EPR to develop the International Consensus
Report on Diagnosis and Management of Asthma (NHBLI, 1992) and the Global Initiative for Asthma (GINA/WHO, 1995). The Global Initiative for Asthma report serves as the consensus document on asthma for countries around the world. In 1995, the NAEPP convened another interdisciplinary panel of asthma experts to review subsequent research since the publication of the first report in 1991. The panel was tasked with developing a set of guidelines for asthma diagnosis and management that could be used by practitioners in diverse health care settings (NAEPP, 1997). The panel has convened periodically to review current literature and update recommendations and guidelines. The latest revision is the EPR-3 maintains that there are four main components of asthma management. However priority of management components has resulted in education moving from fourth to second after assessment. This document is now considered the "gold-standard" guide to asthma care in the United States (NAEPP, 2007).

Outcome Measures for Asthma Management

According to the NAEPP (2007), the goals of asthma management for the adult and child are the same. They are: prevention of chronic and troublesome symptoms, maintain normal or near normal lung function, maintain normal activity levels, prevent exacerbations, optimal utilization of medications without side effects and to satisfy the patient's and families' expectations and goals of asthma care. Asthma education is an important and integral part of asthma management (NAEPP, 2007; Lucas et al, 2001;
Jenkins, 2003; Watkins, 1999; Page, 2000; Marabini et al, 2002; Gibson et al, 2003; Levy et al, 2000; Buzzese, 2001; Amre et al, 2002; Bonner, 2002; McGhan et al, 2003; Durna et al 2003; Janson et al, 2003; Gibson et al, 1999; Turner et al, 1998; Sawyer, 2002; Glasgow, 2003; Guevara et al, 2003; Krahn, 1994). Asthma education increases self efficacy (Guevara et al, 2003; Whitman et al, 1985; Bonner et al, 2002; Buzzese et al, 2001; Lucas, et al, 2001), decreases health care utilization (Amre, 2002; McGhan et al, 2003, Turner et al, 1998; Glasgow et al, 2003; Kelso, 1995), decreases asthma symptoms (Glasgow et al, 2003; Douglass et al, 2002; Wilson et al, 2003; Bonner, 2002; Braganza et al 2003; Janson et al, 2003 and Levy et al, 2000) and improves lung function (Levy et al 2000; Marabini et al, 2002, Glasgow et al, 2003). A basic assumption would be that an effective asthma education program should include these goals as outcome measures. Watkins (1999) suggests that in order to assess effectiveness of asthma programs, outcomes should be measured in terms of physiologic improvement (pulmonary function), clinical improvement (symptom exacerbation, medication usage), human experience (quality of life), and economic impact (cost benefit, analysis, and effectiveness). Most of the studies for this review attempted to measure some of the goals as variables. However, none of the studies reviewed included all of the goals set forth by the consensus documents. There was a great deal of variability noted in study designs.
Asthma Education

There are many studies that address asthma education; however, the question remains unanswered as to whether or not asthma education programs improve clinical outcomes. There are also several questions regarding the efficacy of asthma education. Many previous studies were aimed at increasing self-efficacy and improving knowledge about asthma. Empirical evidence is lacking due to providers limited time to intervene with patients regarding education and practice constraints that are often out of their control, the most common being cost. Evidenced based data is useful to guide asthma care and improve clinical outcomes for patients (NAEPP, 2007).

Does Asthma Education Improve Pulmonary Function?

Improved pulmonary outcomes in terms of large (FEV₁) and small (FEF₂₅-₇₅) airway function is one of the main goals of asthma management, however many of the studies did not include pulmonary function as an outcome measure. For those that did, findings were inconsistent and inconclusive. Levy et al (2000) used a randomized prospective controlled trial to evaluate the effectiveness of adult asthma self-management education following an emergency department visit. The subject pool consisted of 211 adults age 18 and older (mean age 40 years). Patients were randomized into either the control group (n=108) or the intervention group (n=103). Peak
expiratory flow rates increased marginally in each group (no statistical significance between groups).

In a similar effort to evaluate the effectiveness of an asthma education program for adults 18 years of age or older (mean age 50) Marabini et al (2002), conducted prospective randomized controlled trial with 77 patients. Subjects were randomized into a control group (n=40) who continued usual treatment and an intervention group (n=37) who continued usual treatment in addition to receiving patient education. Asthma severity was stratified and for subjects with moderate to severe asthma, pulmonary function as measured by peak flow meter was higher in the intervention group than control at 3 months post intervention (81.2 +/- 16.5 vs. 72.5 +/- 16.6, p<0.05). There was no statistical difference in subjects with mild asthma.

Janson et al (2003) evaluated the effects of a one-to-one asthma education program. The study was a prospective randomized controlled trial of adults between the ages of 18 and 55 (n=65). Subjects were determined to have mild to moderate asthma. Pulmonary function was determined by FEV₁ and eosinophils in induced sputum. The concentration of sputum eosinophils decreased in the intervention group by 67% and increased 17% in the control group (p=.02). FEV₁ increased in the intervention group however, there was no statistical difference between groups.

Guevara et al (2003), conducted a meta-analysis of educational interventions for children and adolescents and found that in four trials (n=258)
education was associated with only moderate improvement in pulmonary function (0.50, 0.25 to 0.75) and in three trials (n=192) there was no effect of education on lung function.

Insignificant and conflicted findings in pulmonary function may be attributed to the fact that the effect size was not big enough. In other words, the subjects were not "sick enough" meaning that the asthma may not have been severe enough to demonstrate a great improvement in lung function during the study period. The researchers rarely reported asthma severity for the group members and where they did subjects were reported to have mild to moderate asthma. Marabini et al (2002), actually stratified the sample to account for asthma severity. For those patients with mild asthma improved lung function was not statistically significant. Another barrier to indicating the effect of asthma education on pulmonary function could be the small sample sizes. Samples may have been too small to show a difference between groups. Also the study periods may not have been long enough to realize an improvement in pulmonary function (Fink, 2001; Watkins, 1999). Most of the aforementioned interventions lasted approximately three months. Inhaled corticosteroids can take four to six weeks to begin to have an effect on pulmonary status. It is also not clear if the subjects were avoiding triggers. Constant exposure to triggers can contribute to lung inflammation in which case, steroids would not be effective in reducing inflammation and improving pulmonary function.
Does Asthma Education Decrease Health Care Utilization?

Gibson et al (2003) and Guevara et al (2003) conducted meta-analysis studies of asthma education for adults and reported conflicting data. The Gibson group evaluated 12 studies and found that there was decreased utilization of the emergency department, decreased unscheduled visits for asthma exacerbation and decreased hospitalizations due to asthma. The Guevara group evaluated 32 studies and found that asthma education had no effect on hospitalizations and that emergency department use decreased with the intensity of the educational program (more sessions resulted in less usage). Lucas et al (2001) reported a 3% decrease in hospitalizations between baseline and year 1 and 2% between baseline and year 2 (p<0.005), emergency department visits decreased 7% between baseline and year 1 and 18% between baseline and year 2 (p<0.005), there was a 19% decline in urgent care use between baseline and year 1 and 48% between baseline and year 2 (p=0.005). Levy et al (2000) studied 211 adults and found that the intervention group had significantly less routine consults with their doctor (p=0.03) and their asthma nurse (p=0.03). Unscheduled visits and hospitalizations were less than the control group, but no statistical difference was seen.

Greineder et al (1995) evaluated the effects of a hospital based pediatric asthma education program for children between the ages of 1 and 17 years over a period of six months to two years (n=53). At the conclusion
of the intervention they demonstrated an 86% reduction in hospital admissions (35 visits per year to 5 visits per year $p<.001$) and a 79% reduction in emergency department visits for asthma exacerbation (72 visits per year to 15 visits per year $p<.001$). In a similar intervention with adults Kelso et al (1995) demonstrated that asthma education was useful for decreasing emergency department visits, using a convenience sample of adult patients seen in the emergency department for asthma exacerbation (n=30). Investigators concluded that post intervention there was a significant decrease in emergency department utilization by the intervention group (from 4.4 +/- 2.7 to 2.6 +/- 2.6 [$p=<0.01$]) compared to (3.4 +/- 2.6 before and 3.5 +/- 2.7 after [$p=0.96$]) in the control group. Post intervention there was a trend toward significant decrease in hospitalizations in the intervention group ($p=0.01$) versus in the control group ($p=.37$).

Even after these studies, the question of whether or not educational interventions decrease health care utilization remains unanswered. Several variables may have contributed to the inconsistent findings. For instance, Confounding variables that may have obscured findings could have been level of asthma severity in patients. Patients with less severe asthma (mild persistent) may not use health care resources as much as patients who are not well controlled and who have moderate to severe asthma. Socioeconomic status may also have affected access to health care, in that individuals without medical insurance or a medical home may have utilized
emergency department services more often. Uninsured individuals tend to have higher asthma morbidity thereby requiring more care (Kelso et al). It is plausible that the emergency department continues to be the sole source of healthcare to the uninsured regardless of the intervention provided. However this remains a question for further scientific inquiry (Kelso et al, 1995).

**How Does Asthma Education Effect Medication Usage?**

While most patients with asthma take similar drugs, pharmacotherapy is determined based on asthma severity. The EPR-3 suggests a step-wise approach for managing adult and pediatric asthma. Asthma severity and related risk are determined, followed by anti-inflammatory therapy. The underlying rationale for this approach is that control of pulmonary inflammation can be achieved with daily use of inhaled corticosteroids (control medication). Once inflammation is controlled the need for short acting beta$_2$-agonists (rescue medication) should decrease (Goolsby, 2003; NAEPP, 2007).

Bonner et al (2002) reported that use of control medications in the intervention group increased significantly (from 80% to 94%) after the educational intervention and decreased in the control group (from 78% to 74%) $p<0.001$. At the conclusion of the study 82% of the intervention group reported adhering to the prescribed frequency of rescue medication use compared to 40% of the control group ($p<0.001$).
Janson et al (2003) reported that at the end of their educational program the intervention group increased steroid use by 20% (from 70% to 91%) whereas steroid use in the control group decreased by 3% (from 65% to 62%) p=0.01. There was no statistical difference between groups for use of bronchodilator. In another study McGahn et al (2003) evaluated an asthma education intervention for school children (n=162) in an urban setting. They reported a significant improvement in both controller medications and appropriately use of rescue medications for both the intervention (56.9% to 63.1% and 68.3% to 88.9% p<0.001) and control group (54.2% to 61.1% and 52.4% to 69.8% p<0.001).

Surprisingly these were only four studies that reported on medication usage. The meta-analysis studies did not report on medication use. The previously mentioned studies reported increased use of controller medications and a decreased or more appropriate use of bronchodilator. However Marabini et al (2002) reported that during the follow up period the intervention group used more rescue medication than the control group.

Studies reviewed for this review are inconclusive regarding the effect of asthma education on medication usage. While some studies report increased use of controller medications, others report no statistical difference between groups. Decreased use of rescue medication is an important indicator for disease control. However, some studies reported decreased usage while others reported increased use.
What is the Essential Content of Asthma Education?

Asthma education is one of the platform goals for effective asthma management, yet patients are not receiving adequate information about asthma and disease management. United States (U.S.) researchers interviewed 2,509 people with asthma or people who cared for a young child with asthma and determined that asthma is poorly managed in the U.S (Asthma In America Study, 1999). In New Jersey 72% of asthma patients felt that there was a need for more asthma education. The survey revealed that 90% of those interviewed did not know the underlying cause of asthma symptoms and 50% did not know that it is possible to prevent asthma exacerbations (Asthma In America Study, 1999). Another study found that parents of children who have asthma felt that the education they received from their child’s provider was either inadequate or hard to understand (Monsour et al, 2000).

Overwhelmingly, studies have demonstrated that asthma education programs do have some positive effects on patients. Patients have increased their knowledge about asthma or demonstrated behavior change (Cote et al, 1994; Monsour et al, 2000; Makinen et al, 1999; Wilson et al, 1999; Owen, 1994; Newhouse, 1994; Durna et al, 2003; Becker et al, 1994; Meng et al, 1998; Alaniz & Nordstrand, 1999; NAEPP, 2007; Lucas et al, 2001; Jenkins, 2003; Watkins, 1999; Page, 2000; Marabini et al, 2002; Gibson et al, 2003; Levy et al, 2000; Bruzzese, 2001; Amre et al, 2002; Bonner, 2002; McGhan et
al, 2003; Durna et al 2003; Janson et al, 2003; Gibson et al, 1999; Turner et al, 1998; Sawyer, 2002; Glasgow, 2003; Guevera et al, 2003; Krahn, 1994). Studies that have included asthma education as part of the methodology vary in regard to the asthma content that is taught. The appropriateness of an asthma educational program will vary depending on the target population. The teaching styles and information that may be relevant for the adult learner in most cases won't work for the pediatric patient (Wilson & Starr-Schneidkraut, 1994).

Experts agree that basic information such as; asthma pathophysiology, medication indication, medication action, and trigger recognition should be included for pediatric asthma education. However, discrepancies still exist among experts such as; length of programs, settings, and who should be teaching the programs. The NAEPP is considered the most widely used asthma education program to date (Wilson & Starr-Schneidkraut, 1994) and for that matter, it is esteemed as the "gold standard" for asthma education. The NAEPP suggests that the following information be included in asthma education (1) Importance of long-term controller medication use (2) correct use of medication delivery devices and monitoring devices such as: nebulizers, metered dose inhalers, dry powder inhalers and spacing devices (3) trigger identification (4) symptom monitoring and (5) how to use the asthma action plan.
AAAAAI (1999) and Laura et al (2002) concur with the NAEPP however they recommend adding content about rescue medication use, symptom recognition, interpretation of peak flow meter data (zones) and how to use the asthma action plan. Becker et al (1994), conducted a systematic review of published pediatric asthma programs and determined that a high quality educational program should meet the following criteria:"

contains accurate, current, and appropriate information; adopts an appropriate learning philosophical point of view; is interesting and attractive to children; is free of cultural, ethnic, age, race, disability and sexual bias; is realistic in cost; is easy to obtain; and demonstrates instructional merit.

Researchers also suggest that an effective program targeted at the pediatric learner should allow the child to demonstrate techniques and skills such as peak flow meter use correct use of medication delivery devices, and management of acute exacerbation. All programs for children should provide positive reinforcement and praise (Becker et al, 1994; Meng et al, 1998; Alaniz & Nordstrand, 1999).

Following a review of several well known asthma education programs, Wilson and Starr-Schneidkraut (1994) purport that asthma education content should include: preventive medication use, trigger avoidance and environmental control, proper use of medication to manage symptoms, how to communicate with health care professionals, how and when to use health care services, and the importance of maintaining one's overall health.
Does Individual or Group Education Work Best?

The NAEPP and AAAAI recommend specific content that should be included in pediatric asthma education programs (pathophysiology, symptoms triggers, trigger avoidance, and medications) however, specifics on how the content should be delivered is left to the educator. While several studies examining the effect of asthma education on variables such as (lung function, knowledge, symptom alleviation, self-efficacy and quality of life) have been published, studies that examine how well the various educational models perform in terms of these outcomes are few.

The studies reviewed for this paper that attempted to measure some clinical outcome after using an educational intervention varied in educational style. Some employed group techniques (Bruzzese et al, 2001; Lukacs et al, 2002), while others used a one to one approach (Marabini et al, 2002; Levy et al, 2000; Kelso et al, 1995; Kelly et al, 2000).

One randomized controlled trial compared the efficacy of two standardized asthma management programs in an adult population. Outcome measures for the programs were medication use, asthma symptoms, respiratory illness, functional status and health care utilization. Subjects were randomized into a group which received the full educational program consisting of a workbook, a one hour one-to-one education session, attendance at two asthma support group meetings and personal follow up from a counselor at 1, 2, and 4 weeks after the initial education session. The
second group received a 15-20 minute one-to-one education session, telephonic counseling one week later and a follow up letter two weeks after the telephone session. A control group was formed of patients who received only their usual care and standard education from their physician. At the end of the study period researchers found that, patients in the educational programs did no better than patients in the usual care group. However, for all outcome areas the patients in the treatment group that received the more involved education consisting of a one hour one-to-one teaching session, support group attendance and repeated telephonic counseling sessions did slightly better than those who received the abbreviated care.

In a study of 323 adults with moderate to severe asthma, Wilson et al (1993) compared a four-session small group educational program and individual teaching using the same instructional content with a self-study workbook and usual medical care without any special education. The researchers determined that the small group and individual education designs were more effective than the control conditions for improving asthma management outcomes. They also determined that the small group method was much more cost effective and was the only format associated with decreased health care utilization for acute exacerbation.

Glasgow et al (2003) conducted a randomized controlled trial of 174 children in Australia to determine the effectiveness of two asthma education programs. Children were randomized to an intervention group that received
asthma education from their general practitioner in three visits and those who received asthma education from their general practitioner in a recommended six visits. Outcome measures were: rates for physician visits, written action plan, completion of the three visit program, rates for ED visits, days absent from school, symptom free days activity limitations, medication usage.

At the end of the study period researchers found that the children who received asthma education in three visits had: more preventive visits (3.8; 95% CI 1.9 to 7.6 \( p=0.0001 \)) written action plans (2.2; 1.2 to 4.1 \( p=0.01 \)), completed the program (24.2; 5.7 to 103.2 \( p=0.0001 \)), increased use of asthma action plans (5; 3 to 41), decreased ED visits (0.4; 0.2 to 1.04 \( p=0.0001 \)) and increased use of spacing devices (2.8; 1.6 to 4.7 \( p=0.0001 \)). There was no difference noted in symptom free days and school absenteeism.

Velsor-Freiedrich et al (2005) conducted a study with 52 minority school age children 8-13 years of age to evaluate the Open Airways for Schools program. At the time of the study Open Airways for Schools was a six week asthma education program designed for small groups of children. Outcome variables were asthma knowledge, self-efficacy, general self care practices and asthma self care practices. Four inner city schools were randomly assigned to either the treatment group or the control group. Researchers collected data at baseline, weeks 2, 5, and at 12 months after
the educational intervention. At the end of the study period there were 24 children in the control group and 28 children in the treatment group.

The children in the treatment group attended the Open Airways for Schools program for six weeks. At the completion of the program, they had five follow up visits with the nurse practitioners at their school. During the follow up visit the nurse practitioner assessed the student's asthma health, current medication use and availability, asthma symptoms, emergency department visits and hospitalizations. Students were asked to demonstrate medication and device use. The nurse practitioner also reinforced educational information from the Open Airways curriculum. If necessary, adjustments were made to the child's asthma management plan. The control group did not participate in the educational program. While the authors did not directly address this what happened with the control group during the last five months of the study, one may assume that the children in the control group did not receive any other attention. At the end of the twelve month study period, researchers found that the students assigned to the treatment group scored higher than the control group over time on measures of asthma knowledge, asthma self efficacy, and general self care practices.

Despite all of the studies to date, the question of whether group or not individual education works best still remains. Several studies have yielded conflicting and inconclusive data. One study suggests that shorter programs are more effective while another suggests that a lengthier program is more
beneficial (Glasgow et al, 2003; Velsor-Friedrich et al 2005). While detailed lecture style education may work for adults, children fare better with shorter more interactive education (Becker et al, 1994). These remaining gaps in the literature may be due in part to sampling. Many of the studies used convenience samples. In doing so subjects across the illness spectrum were included. The inclusion of subjects with milder disease may have adversely affected the study outcomes because change in condition may have been more difficult to detect. Sample sized varied greatly. Studies with smaller subject pools may have failed to detect a difference in intervention.

What is the Best Setting for Asthma Education?

The studies included in this review had educational interventions that were conducted in a variety of settings: hospitals (Levy et al, 2000), emergency departments (Kelso et al), general pediatrician offices (Glasgow et al, 2003; Lukacs et al, 2002), specialists office (Bailey et al, 1999; Durna & Ozcan, 2003; Kelly et al, 2000), malls (Alaniz & Norstrand, 1999), outdoor camps (Meng et al, 1998) and elementary schools (Bruzese et al, 2001). Wilson & Starr-Schneidkraut (1994) found evidence that when asthma education is incorporated with the regular clinical encounter it is less effective. This may be due in part to the limited time of the visit. There were no studies reviewed that compared efficacy of educational programs in relation to the location of the interventions.
Asthma Action Plan

The asthma action plan is an important part of asthma education and self-management. The action plan is a simple set of guidelines that are specific for the patients' needs. The action plan that is suggested for use by the NAEPP is derived from the evidence-based guidelines of the EPR-3. The action plan uses a metaphorical traffic light approach to asthma management also referred to as the zone management plan. The zone metaphor uses the colors green, yellow and red to educate patients on how to manage their symptoms. Green indicates that the patient is doing well and the individual's peak flow meter reading is at 80% or better of his personal best (best peak flow meter score when symptoms are under control). Yellow indicates that the asthma symptoms are getting worse and the peak flow meter reading is between 50% and 80% of his best score. Red indicates a medical emergency and the peak flow meter reading is less than 50% of the individual's personal best.

The health care provider is supposed to work with the individual to help them determine his/her personal best number and then based on this number specific instructions are given in writing regarding medication use, activity limitations and when and where to seek medical care. Ideally, children are supposed to have an action plan for home, for school and for sports activities. AAAAI recommends that everyone involved in the care of the child in the
various settings should have a current copy of the child's written asthma action plan.

What Effect if any does the Asthma Action Plan Have on Morbidity?

Turner et al (1998) conducted a prospective randomized controlled trial of 92 adults to determine the effectiveness of peak flow meter readings versus asthma symptoms to guide self-management. Outcome measures were spirometry, symptom scores, quality of life, medication use, health care utilization, and morbidity as determined by health care utilization. Patients were randomized into either the symptom group or the peak flow meter group. At the conclusion of the study investigators determined that each group had a significantly lower use of inhaled bronchodilators (rescue medication) ($p<0.008$ for both groups) and increased use of controller medication (inhaled steroids) ($p<0.001$). According to the researchers adherence to the asthma action plans was 65% in the peak flow meter group and 52% in the symptom group. Morbidity was reportedly similar between groups with the exception of the peak flow meter group making fewer unscheduled doctor visits. This study is important because it demonstrates that symptom based asthma action plans can be efficacious. While the study was conducted with an adult population, these findings are of particular interest to the pediatric population. Very young children are not able to use peak flow meters or perform spirometry properly therefore, parents must manage symptoms by proxy interpreting symptoms and then taking the appropriate action.
Douglass et al (2002) employed a qualitative design to investigate the perspectives of patients with asthma on the use of the asthma action plan. Sixty-two adult participants were interviewed. After data analysis, investigators determined that the study participants viewed the asthma action plan positively. Most did modify the plan without physician consent according to their own experience with their disease and symptoms. Findings of this study conflicted with an earlier qualitative study in which participants indicated that asthma action plans were not useful (Jones and Adams, 2000).

Cowie et al (1997) studied 150 adults for a period of six months to determine the effect of symptom based asthma action plans and peak flow based action plans on asthma symptoms. A control group was comprised of patients who did not receive either type of plan. Investigators found that there was an overwhelming reduction in ED visits for the peak flow group only (p=0.006). There was no significant difference in ED visits for those who used the symptom-based plan or for the control group.

What Works Best: Written vs. Verbal Plans?

In a study to determine the patterns of chronic outpatient management of moderate to severe adult asthma patients in an urban setting, Harter et al (1996) found that less than half of the subjects (28%) had been given an asthma action plan by their health care providers. Of the 28%, only a few (exact numbers not reported) of the patients had written asthma action plans,
the others were told by their healthcare providers to go to the ED if asthma symptoms worsened.

Gibson et al (2000) reviewed 36 studies that compared adult patients with asthma who participated in self-management, in the form of education and physician follow up, with those who received usual care. Usual care meant whatever the patient's provider did or did not do for their patients with asthma. The researchers found that those who were active participants in their own care had significantly fewer ED visits, hospitalizations, unscheduled visits to their health care provider, nighttime symptoms and fewer missed days of school and work. Subjects also reported improved quality of life. There was no difference in lung function between the groups. Researchers also found that overwhelmingly the self-management programs that utilized a written asthma action plan were far more effective than those that did not. There were no studies in this sample that specifically measured the efficacy of asthma action plans on pediatric asthma outcomes.

The following variables will not be measured in of this study however they are discussed because understanding them is relevant to the discussion of asthma as a chronic disorder in children.

**Psychosocial Factors**

Wade et al, (1997), reported the psychosocial protocol developed by the National Cooperative Inner-City Asthma Study (NCICAS) Phase II. In this multi-center trial researchers investigated factors that contributed to asthma
morbidity among inner city children. Their work has resulted in the development of a framework that attempts to link psychosocial factors to outcomes. Both distal and proximal factors were identified. Distal factors included social support and environmental stress. Proximal factors included: (1) psychological adjustment of the adult caring for the child, (2) family functioning, (3) the psychological adjustment of the child, (4) various aspects of asthma management such as the caregiver’s knowledge, attitude and beliefs about asthma, the caregiver’s ability to problem solve and their ability to be responsible for carrying out the tasks of asthma management. These factors are particularly important because asthma disproportionately affects minority children especially those who live in urban areas (Aligne et al, 2000; Bousquet et al, 2005). This constellation of factors supports the supposition that asthma is extremely complex and appropriate care of this disorder entails much more than medication dispensing. Providers must consider all the proximal factors discussed when developing a plan of care for the pediatric patient.

**Social Support and Life Stress**

Children who live in urban areas often experience greater amounts of life stress due to low socioeconomic status, and other factors associated with urban living (Wade et al, 1997; Weil et al, 1999). Stressful life events have been associated with poor health outcomes in urban minority children. It is believed that excess stress negatively affects the immune system thus
making the individual more susceptible to physical illness. Excess levels of stress also decrease the ability of the child and the caregiver to manage asthma symptoms effectively, thus resulting in increased morbidity (Weil et al, 1999). Social support has demonstrated a "buffering" effect on life stress and physical and psychiatric illnesses (Weil et al, 1999) in that those children and caregivers who experience more social support are better able to manage asthma symptoms even within high levels of life stress.

**Mental Capacity of Caregiver**

The psychological health of the caregiver may affect a child’s asthma morbidity because caregivers who are mentally impaired may employ less effective parenting techniques, have inappropriate use of healthcare services, and have difficulty adhering to prescribed medical regimens for the treatment of asthma. In a study of 1,528 children ages 4 to 9 years of age, Weil et al (1999) examined the relationship between psychosocial factors and asthma morbidity in inner city children. The researchers found a positive correlation between children’s hospitalization and the caregiver’s mental health. Children of caregivers whose scores exceeded the cutoff on the parental psychopathology measure were 1.78 times more likely to be hospitalized than those who had caregivers that scored below the cutoff (15% vs. 9%; p<.01). Researchers also found that children who had clinically significant mental health issues were more likely to experience symptoms (p<.01) than children who scored below the cutoff on mental health measures.
In their investigation of psychosocial factors that contribute to asthma morbidity among urban dwelling children, The National Cooperative Inner-City Asthma Study (NCICAS) (1997), found that 50% of the caregiver's scores on the Brief Symptom Inventory, a psychological measure, indicated that the caregivers were suffering from extremely elevated levels of psychological distress (56.02. vs. the norm of 50) severe mental illness. Caregivers in the sample also reported increased life stress during the study period (Wade et al, 1997).

**Race, Ethnicity and Socioeconomic Status**

Asthma mortality rates increased gradually during 1988-1995, however disparities in race continue to persist because mortality rates among blacks in the United States remain high (CDC, 2002). Rates for ED visits were more than three times those for their white counterparts, with the youngest children having the highest rates. Blacks in the U.S. have consistently higher rates for physician office visits and hospitalizations as well. Wissow et al (1988) reviewed hospital discharge data for the state of Maryland in an effort to determine whether race and poverty are associated with the rate of hospitalizations for pediatric asthma. The researchers used Medicaid enrollment as a measure of poverty for Black and White children. Researchers found that the discharge rate for Black children with asthma was 2.5 times those of White children in the youngest age groups and nearly five times greater for adolescents ages 15-19 years old. They also found that the
Black children had a shorter mean length of stay when compared to the White children (3.33 vs. 3.78 days) and were more likely to be admitted urgently (88.4% vs. 80.1%).

In an effort to further evaluate socioeconomic status and morbidity researchers compared discharge rates for Black children enrolled in Medicaid and Black children who were not enrolled in Medicaid and they found that the discharge rate for Black children enrolled in Medicaid was twice that of the non-enrolled Black children (5.68 vs. 2.99). Researchers also compared discharge rates for the most impoverished Black areas with the most affluent White areas and found that discharge rates for the Black areas was more than 10 times that of affluent areas (7.54 vs. 0.68.) These findings support the assumptions of Malveaux and Fletcher-Vincent (1995) that the disparity of morbidity and mortality are more closely associated with poverty than race or ethnicity.

Krishna et al (2002) interviewed the adult caregivers of 457 Canadian children between the ages of 3 and 4 years to determine the effects of socioeconomic status on asthma severity, hospitalization rates and ED use. The main measure of socioeconomic status was the father’s occupational group. Occupations were classified into four subgroups. Researchers found that children whose fathers belonged to the lower occupational groups (LOG) were more likely to be hospitalized when initially diagnosed when compared to children whose fathers belonged to the upper occupational groups (UOG)
Care providers of the LOG children were less likely to report anti-inflammatory medication use (controller medicine) than those of UOG (17% vs. 34%). Interestingly researchers also found a difference along racial lines. Non-White children were less likely than White children to use anti-inflammatory medications (2% vs. 17%) and less likely to visit their physicians for routine care (3% vs. 15%). The researchers found no statistical significance in ED use. This finding is a stark contrast to published findings with US subjects. They report that this contrast is most likely because Canadian children have better access to health care via the socialized medical system.

Low income has also been correlated with the under diagnosis of asthma (Speight et al, 1983), decreased use of preventive care (Strunk et al, 2002; Anderson et al, 1981; Krishna, et al, 2002) and increased use of ED services (Rand et al, 2000). Therefore, it makes sense that asthma education for minority children of low socioeconomic status is both beneficial and necessary in order to alleviate the personal and societal burden of pediatric asthma.

Environmental Factors

Children who live in urban areas are most adversely affected by asthma. Clinical studies have shown that people who reside in urban areas, particularly economically depressed persons comprise a high risk for asthma morbidity (Weiss et al, 1990; Weiss et al, 1992). Rand et al (2000) studied
children from 42 elementary schools in Baltimore, MD (21) and Washington, D.C (21) (n=329 children) and found that patients who limited dust mite exposure by using mattress covers were less likely to report an ED visit during the study period (0.5; CI 95% 0.3-9 (p=.032)). The researchers felt that mattress cover use was exemplar of better asthma knowledge and management.

Using a convenience sample of 75 children ages 2 months to 10 years, De Vera et al (2003) found that exposure to cockroach allergen was significantly correlated with episodes of wheezing. This data supports the findings of Rosenstreich et al (1977) who also found that over a 12-month period of time, children with asthma who were allergic to cockroach allergen had higher morbidity when compared with those children who were not allergic. Morbidity was measured in terms of hospitalizations (0.37 vs. 0.11) (P=0.001) and unscheduled medical visits (2.56 vs. 1.43) (P=<0.001).

Barriers to Asthma Management

The NAEPP guidelines provide clear and explicit direction regarding the management of pediatric asthma. Despite these guidelines, asthma morbidity and mortality continue to rise in children. More alarming is the fact that despite improved treatment measures and evidence based treatment guidelines minority children, particularly Blacks continue to be negatively affected at an alarming and disproportionate rate when compared to White and Hispanic children (CDC, 2002). Given all the increased knowledge,
pharmacological and device breakthroughs within the last decade there still remains a disconnect between what ought to be done and what patients actually do. In an effort to improve health outcomes for pediatric asthma, health care providers often speculate on the barriers to pediatric asthma care.

In an attempt to identify perceived barriers to asthma treatment in urban minority children, Monsour et al (2000) utilized the focus group method to interview the parents of 47 children diagnosed with asthma. According to the researchers, all of the participants identified themselves as Black. Forty-five percent of the children had mild or intermittent asthma and 55% had moderate to severe asthma. After analyzing the transcripts several categories and subcategories of barriers were identified. The major issues that surfaced with regard to patient/family factors were: knowledge/lack of knowledge regarding asthma, asthma medications, and their use (20%), parental attitude toward disease (7.4%) and compliance/noncompliance of child with parent’s recommendations (6.5%). Major health care systems factors included type of insurance if present (4.8), presence/absence of insurance (2.5%) and primary location for asthma care (2.5%). Health care provider factors included education regarding asthma, asthma care, and medication use given in an understandable manner (6.8%), general satisfaction with and trust in the child’s health care provider/lack of trust or dissatisfaction with the child’s provider (2.3%), continuity/lack of continuity with the child’s provider (2.3%). Environmental factors included
knowledge/lack of knowledge regarding asthma triggers (14.6%), available support from child's school (8.6%), financial constraints such as money for transportation and medications (2.1%).

Rose and Garwick (2003) interviewed the caregivers of American Indian children ages 6 months to 9 years living in an inner city. Caregivers were interviewed individually for a period of approximately 90 minutes. Tapes were transcribed and analyzed for content. The barriers were reported by major theme category in descending order. The top three provider and individual barriers were: amount and quality of information, not listening to caregivers or taking them seriously, delays in diagnosis and treatment. Provider/system barriers were ineffective school response, traditional care providers not being available, busy clinic. Condition related barriers included seasonal changes, flare-ups at night, unexpected flare-ups. Family caregiver barriers were fear, lack of understanding about asthma, role strain. Socioeconomic barriers included transportation problems, difficulty paying for childcare, transportation and medication, insurance constraints. Environmental barriers were winter weather and nighttime episodes.

Understanding the barriers to asthma management as perceived by the patient is paramount to having a successful outcome for pediatric patients. Often times educational interventions are designed with little regard to the patient's needs in terms of time, location and transportation. As one considers the previously mentioned barriers as perceived by the
patient/caregiver, the location of asthma education, content and assessment of knowledge and skill transfer become very important. Other issues to consider would be patient’s ability to obtain necessary resources such as medications and monitoring devices.

Healthcare Access

After a thorough analysis of the literature, Gulzar (1999), determined that health care access refers to a patient’s ability to obtain needed health care that is both of high quality and affordable in a timely manner. Research has shown that people who have access to health insurance have better access to health care than those who are uninsured (Goldman et al, 2004; Rosenbach et al, 1999; Weinich et al, 1998).

Rosenbach et al (1999) conducted a two phase telephone survey of children with asthma. Subjects were enrolled in managed Medicaid demonstration programs in three states: Florida, Maine and Michigan. During the first phase, researchers interviewed the parents of 4,420 children and in the second phase they interviewed 3,504 children. Researchers found that the children in the Medicaid programs had higher rates of physician visits, more preventive visits, and fewer ED visits when compared with children who were uninsured. These findings are important because they demonstrate that access to health care does make a difference for children.

Interestingly researchers learned that even when children had managed Medicaid they continued to have unmet need (child needed at least
one type of health care service, but did not receive it), when compared to children with traditional Medicaid and private insurance. Even so, they fared better than those children who had no insurance. These findings also confirm the perceived health care barriers regarding insurance/access issues as indicated by parents in the previous section.

To better understand how insurance access affects pediatric health status, Weinich et al., (1998), analyzed the 1996 Medical Expenditure Panel Survey (MEPS) data. Data was collected from 9,400 households. Analysis revealed that Hispanic children are more likely than children of other racial groups to be uninsured and lack a usual source of health care. The parents of these children also more likely to report that they were in fair or poor health.

Researchers also found that children under the age of six were least likely to have a source of health care (5.5%) while adolescents were most likely to be without a place to go when they need care or medical advice (14.5%). Overall, Hispanics and Black children were less likely to have a usual source of health care when compared to their White counterparts (17.2% and 12.6% vs. 60%). Data revealed an association between socioeconomics and health care access. According to the researchers, one in ten children was without medical care because their parents could not afford it. Forty percent of the respondents reported having a provider who did not have night or weekend office hours and 22% reported that the provider
was difficult to access by telephone. Again, these findings support the reported perceived barriers to health care as reported by Rose and Garrick (2003).

Goldman et al. (2004) analyzed a data set of pharmacy and medical claims for the years 1997-2000 in order to determine how changes in co-payments affected drug usage for adult patients with chronic illness. The data set was comprised of 30 large US employers with 528,969 beneficiaries. Chronic illness was divided by diagnosis and insurance plans were divided into four tiers (subgroups). Tier 1 represented the most generous plans with co-payments that averaged $6.05 per prescription. Tier 2 co-payments averaged $6.31 for generic drugs and $12.85 for brand drugs. Tier 3 co-payments averaged $8.91 for generic drugs and $33.02 for brand. Adults with asthma comprised 1.4% of tier 1 patients, 1.2% of tier 2 patients and 2% of tier 3 patients. Patients with asthma comprised 9% of those with more than one filled prescription. On average, those patients received 117 days of medications. When co-payments were increased, there was a 20-day reduction in supplied asthma medications and a 30-day reduction in medication used to control allergic rhinitis.

These findings are significant because corticosteroids are part of the preventive asthma regimen. When patients fail to take their controller medications, exacerbations are more likely to occur. For those patients
whose asthma is associated with environmental allergies, the medications for allergic rhinitis are very necessary for control.

The subjects from this study were adults however the findings can be applied to the pediatric population because children rely on their parent's resources for survival and health maintenance. If their parents do not have the financial resources to purchase medications, the children will not receive the medications they need to control and prevent asthma symptoms.

These findings clearly indicate an inverse relationship between health care access and child health status. Children with access to health care fare better than those who do not have health care. Yet, children with public insurance continue to have unmet health care needs. For the child with asthma, this is significant given the complex management that is often needed. In addition to regular preventive care by the primary pediatrician, these children may need to see a pediatric pulmonologist or an allergist. Comprehensive education and monitoring along with medication are all necessary components of successful asthma management. Therefore, in order for asthma to improve it is imperative that these children have access to adequate health care.

**Special Pediatric Issues**

Several factors can affect the researcher's ability to carry out sound research investigation in pediatric populations. The various developmental stages are an important consideration because young children desire to be
active participants in their health and they are capable of being more involved in the management of their chronic disorders. This study is interested in the ability of school age children between the ages of 8 and 12 years. According to Vessey and Mebane (2000), these children are typically transitioning from a relationship with their parents and other family members to one with their peers. During this age, the child is beginning to identify with their friends and as such their friends have a greater impact on the child’s self esteem. Those things that cause the child to be singled out or seen as different can affect their relationship with their peer group.

**Parent vs. Self Care**

Other issues such as when a child is able to safely participate in his or her preventive care also exist. At what age should this occur? A review of the current literature failed to yield published data regarding children with asthma and the transition of their care from that delivered solely by the parent to that in which the child has more responsibility. A wider search including all chronic disorders in children also failed to yield definitive information regarding children with chronic diseases and self-management. Children with chronic diseases such as asthma will have the lifetime responsibility of caring for their chronic illness while maintaining a healthy and productive life. The sequela poorly managed asthma during childhood can potentially have long lasting physical and mental ramifications such as advanced disease, airway remodeling, and depression. Increased knowledge and self-management
skills may lead to improved self-management skills and fewer exacerbations (Fielding & Duff, 1999).

Gaps in Literature

A review of the current literature that pertains to pediatric asthma education and clinical outcomes has revealed that there are no recently published studies that report a clear relationship between asthma education, in particular the Open Airways for Schools Program, and clinical outcomes in children. There are conflicting and inconclusive data regarding the type of asthma education that is beneficial in terms of length of educational program and setting. Few studies have measured clinical outcomes in children and none have measured clinical outcomes in terms of specific lung function measures such as FEV₁ and FEF₂₅₋₇₅.
CHAPTER THREE

METHODOLOGY

Design Strategy

The design strategy for this pilot study consisted of a classic experimental design. This study was approved by the IRB of Columbia University (Appendix A) and Newark Beth Israel Medical Center (Appendix B). Consentig subjects were randomized to either a control group and received usual asthma care that was provided by their primary care provider or a treatment group that received asthma education. Pre-test/post-test measures were obtained for both groups. This design was selected because experimental designs have the highest degree of internal validity and they allow the researcher to infer causal relationships (Brink & Wood, 1998). The high degree of internal validity also enhances the researcher's ability to predict and control the phenomenon of interest. In addition, when executed properly, experimental designs increase the researcher's ability to generalize findings (Brink & Wood, 1998). Classic experimental designs while powerful are often quite involved. Therefore before a full scale experimental study was initiated a pilot study was undertaken.

The classical pilot study is conducted to determine the feasibility of a larger study. The data from the classical pilot study is not used in the final analysis and therefore it cannot be used to test hypotheses. The pilot study requires a minimum of twenty subjects and is used to determine and or
recalculate the overall sample size (Peat, 2002). The pilot has a small effect on the alpha of the study however by providing a more accurate estimate of the sample size it has a significant effect on both the power and the efficiency of the study. The pilot study is used to: ascertain problematic issues that may occur within the study intervention, determine the reliability and practicality of the instruments, ascertain problematic issues with the recruitment process and determine the feasibility of continuing with a larger scale study. This researcher wishes to continue this study on a larger scale thereby launching a program of funded research.

Details regarding sampling, randomization, and the intervention will be discussed in detail later in this chapter.

Theoretical Framework

Orem’s Theory of Self Care Deficit was used as the theoretical underpinning for this study. This theory is part of a larger theoretical framework conceptualized by Dorthea Orem. The basic premises that support the framework were first introduced by Orem in 1959 when she wrote a report “Guides for Developing Curricula for the Education of Practical Nurses” (Fawcett, 2000). In 1971, the first edition of Nursing: Concepts of Practice was published. Orem has continued to develop the theory. Her continued work has resulted in a grand nursing theory or framework that is comprised of three theories: Theory of Self-Care, Theory of Self-Care Deficit, and the Theory of Nursing Systems. The Theory of Self-Care addresses
individual factors and conditions, the Theory of Self Care Deficit addresses health care institutions and the Theory of Nursing Systems encompasses the social and interpersonal systems of the individual and the professional systems of the institution.

Within the Theory of Self Care, self-care is defined as personal care that individuals require each day to regulate their own functioning and development. Self care is learned, goal-oriented activity that is directed toward one’s self or the environment to regulate factors that affect their functioning, health and well being (Orem, 2001). Self Care Agency is defined as the complex, developed capability that enables the patient to provide self-care (Orem, 2001). In the case of asthma, examples of self care would be appropriate use of control medications, trigger avoidance and initiation of care when symptoms exacerbate.

Orem also mentions that certain factors, either intrinsic or extrinsic, must be considered before self-care can occur. She calls these factors Basic Conditioning Factors. They are age, gender, developmental state, health state, sociocultural status, health care system factors, family systems factors, patterns of living (activities of daily living [ADL]), environmental factors and socioeconomic status. In the case of asthma, examples of basic conditioning factors would be the persons age, race, level of asthma severity (moderate to severe persistent), access to health care or medical home. Environmental
Factors would include trigger exposure such as tobacco exposure, roaches, rodents and exposure to other environmental pollutants.

There are several major philosophical assumptions that underpin the Self Care Framework. Only the assumptions that are pertinent to this study will be discussed. The first assumption is that chronological and developmental age, culture, and previous experiences affect the individual's use of symbols and the meanings that match them. This is important to the phenomenon of interest because young children have very few "life experiences" to draw upon. Previous encounters with the health care system and healthcare providers may be perceived as negative. Prior to age eight, the child's memory of preventive health encounters may be marked by "painful" experiences, mainly immunizations. Furthermore, for the child with asthma, previous encounters may be perceived as traumatic especially if the child's caregivers rely on crisis care. ED visits during acute asthma attack can result in venipuncture for intravenous therapy and assessment of blood work, injections of corticosteroids, arterial puncture to assess oxygenation, or intubation to maintain or restore adequate ventilation and respirations. Minority children have these experiences more than White children (Halfon & Newacheck, 1993).

The second assumption of value is that the ability of the nurse to be with clients and communicate with them effectively requires that she incorporate and use meaningful language and other forms of communication
and has knowledge of appropriate socio-cultural practices. This is important to remember when nurses from the dominant culture interact with minority clients.

A third assumption is that individuals are capable of performing self-determined actions even when they feel an emotional pull in the opposite direction. For the child at the developmental age of early school age, this pull may be a belief that he is not capable of performing the action or a fear of failure. Therefore, he may not attempt self-care behaviors. It is also important because many adult caregivers and health care providers believe that children are not capable of performing therapeutic self-care activities, when in fact they can. Children at this age are capable of determining that they are experiencing increased asthma symptoms and should be encouraged to relay this information to an adult so that proper intervention for asthma management can occur.

A fourth assumption is that in order to act, an individual must consider available actions and then choose one. This is important because the self-management of asthma involves the review and selection of options that are prescribed in an Asthma Action Plan. The child will need to use a peak flow meter or recognize symptoms in order to determine the severity of an exacerbation. Based on the severity of symptoms he will select from treatment options that may range from maintaining prescribed therapy, increasing frequency or dose of drug therapy or seeking medical treatment.
These actions are possible with minimal assistance provided by the adult caregiver.

A fifth assumption is that an important part of care is teaching. This involves the nurse. Nursing is a form of assistance that is rendered by a nurse to individuals who are in legitimate need of assistance. Nursing is characterized by the nurses' knowledge of the discipline and the nurse's capabilities rather than by where nursing takes place. Orem also postulates that the results of nursing are characterized by the nurse's abilities to meet the existent and emergent needs of the client as well as assisting the client to develop self-care abilities. This assumption is extremely critical when one considers pediatric asthma.

Assumptions directly related to this study are that children age 8-12 years old can be taught to participate in asthma self care and they can reliably self-report symptoms and self care interventions.

Sample

The sample for this pilot study was comprised of school-age children between the ages of 8 and 12 years of age who lived in an urban environment and had moderate to severe persistent asthma as determined by the NIH guidelines for step-wise management of asthma. The primary investigator (PI) or trained designee determined the subject's asthma severity based on a review of symptoms (frequency of symptoms during the day and night during the week or within a month), medication use (prescribed use of inhaled
corticosteroids) as determined by the NIH guidelines for step-wise management of asthma, or review of medical chart to determine if there was a documented diagnosis of moderate or severe persistent asthma.

Based on the precepts of the Central Limit Theorem a sample size of 30 subjects is appropriate for a pilot study. The Central Limit Theorem states that the researcher can be assured of a near normally distributed sample if: sampling occurs from a normally distributed population, sampling occurs from a population whose functional form is not known, and sampling is from a non-normally distributed population. Therefore in most practical situations, a sample size of 30 subjects is appropriate (Daniel, 1999; Peat, 2002). While this small sample size is sufficient for a pilot study, a limitation for the study is that the study will have decreased power and inference will be greatly limited due to the small size. The Java Applets computerized program to determine sample size and power was used to determine the sample size for this pilot study. According to the program for a power of .80 and alpha of .05, 20 subjects were required. To account for possible attrition, the PI decided that 30 subjects would be recruited for this pilot study. Given the outcomes of this pilot, the author wishes to proceed with this study after the pilot phase. Most funded research requires that the researcher conduct and present the findings of a pilot study. This is done to ensure accountability of resources and accurate findings (Teijlingen van and Hundley, 2001). The Java Applets computerized program was used to determine an appropriate sample size for
a full randomized controlled clinical trial with three measurement times. For a repeated measure ANOVA with a power of .95, alpha of .05, and three levels of treatment the program determined that a total of 64 subjects would be needed (Lenth, R. V. http://www.stat.uiowa.edu/~rlenth/Power/). One of the benefits of a repeated measure design is that it decreases the amount of subjects that are required for a study especially when subjects are difficult to recruit (SAS Library ucla.edu/stat/sas/library/repeated_ut.htm).

Recruitment

Recruitment began immediately upon NBIMC IRB approval and ended when the desired number of subjects had been recruited. Subjects were recruited from Children's Hospital of New Jersey at Newark Beth Israel Medical Center (NBIMC) catchment area. NBIMC is part of the Saint Barnabas Health Care System. The Saint Barnabas Health Care System is the largest health care system in the state of New Jersey. NBIMC is a 671-bed regional health care facility located in the north-west section of Newark. The surrounding neighborhoods are comprised of low income African American and immigrant families. Dwellings are older and many have been converted from single-family homes to multi-family units. The hospital's emergency department provides care for many area residents who have a diagnosis of asthma. During 2009, the pediatric emergency department provided care for more than 3,000 children.
Information brochures and recruitment flyers were given to attending and private pediatricians who attended pediatric grand rounds at the medical center. The same flyers were also posted throughout the hospital in the cafeteria, the pediatric emergency department waiting area, the pediatric inpatient unit, the pediatric intensive care unit, the pediatric outpatient clinic. Flyers and brochures were also placed at offsite locations such as local churches and Boys and Girls clubs. Information was also placed on the NBIMC intranet and in the employee newsletter. Several school-based health centers refer patients to Children’s Hospital of New Jersey for care. The providers in these facilities were informed of the study and given information, posters and flyers regarding recruitment.

Trained nurses, residents and physicians gave recruitment flyers or brochures to parents who fit the criteria for study inclusion. Interested parents and their children were asked to complete the contact information section of the brochure or to contact the PI directly at the phone number listed on the flyer regarding participating in the study. If the parents left the brochure information with the staff the information was forwarded to the PI by interoffice mail. Nurses from the inpatient units also collected information and forwarded the completed brochures to the PI or they called and informed the PI that a patient had been admitted for asthma exacerbation and fit the study criteria. On a few occasions, parents called the contact number on the poster and asked to have their child enrolled in the study. The PI met with each
potential subject to determine eligibility. Once eligibility was determined, the PI obtained consent and assent for the study. Subjects were immediately randomized to either the control or intervention group. Randomization was done by having the participant select a small brown envelope. The envelope contained a white card with the word "intervention" or "control" written on it. Seventeen of each envelope was prepared for a total of 34 envelopes. Extra envelopes were prepared for each group to accommodate over sampling as a way to safeguard against attrition.

A total of 32 subjects were recruited for the study. Seventeen were randomized to the control group and fifteen were randomized to the intervention group. The parents of two subjects who were randomized to the intervention group came to only one education session. Reminder phone calls were made to the parents asking them to bring their child to the education program. One parent stated that the traveling and frequent meetings were too much. The other parent had transportation issues, but wanted her child to attend. She asked if the PI would provide transportation for the child. Due to liability issues and the fact that the parent was not willing to accompany the child to the sessions even if transportation was provided by the PI, it was determined that it would be best that the child not participate in the study.

Inclusion Criteria

To be considered for this study, subjects had to meet the following criteria:
• 8 to 12 years of age at the onset of the intervention
• Speak English fluently
• Able to read English
• No documented learning disability
• Documented diagnosis of asthma – at least moderate persistent
• Presently prescribed inhaled corticosteroids
• Access to a telephone
• Able to participate for the entire study period

Exclusion Criteria
• Documented learning disability
• Unable to read English
• Other underlying lung pathology (i.e. Cystic Fibrosis, Primary Ciliary Dyskinesia, etc.)
• Previously attended Open Airways for Schools training
• Not prescribed inhaled corticosteroids
• No telephone access

Study Protocol

Once criteria for inclusion had been determined and both assent and consent were obtained, the subjects were randomized into either the control or intervention group. Subjects in both the control and intervention group were asked to complete a demographic questionnaire that determined: medication use, school absenteeism, symptom severity and environmental
factors. Baseline spirometry measures were also obtained. All subjects completed the Pediatric Asthma Quality of Life Questionnaire (PAQLQ), Child Asthma Control Test (CACT) and an asthma knowledge test prior to the start of the intervention. At the conclusion of the intervention (three weeks later – T2) both groups repeated the asthma knowledge test, CACT, spirometry and the PAQLQ. These measures were repeated again three weeks after T2 or six weeks after baseline (T3). Once the subjects completed all sets of measures they received a participation prize which consisted of a gym bag.

The intervention period lasted for three weeks. The educational intervention consisted of three, one and a half to two-hour, small group, educational sessions that followed the Open Airways for Schools Curriculum. The intervention was run at two consecutive intervals. The first intervention group consisted of eight subjects and the second group consisted of seven subjects. Each group had one child drop out for reasons mentioned previously.

Subjects in the control group completed instruments and measures immediately after consenting to participate in the study. After that the subjects received only attention via weekly phone calls. The purpose of the calls was to remind the subject that they were still involved in the study and to schedule follow up appointments for repeated measures. Phone calls were made by the PI or a designee. When a designee made the attention calls a script was read to the subject (Appendix C). Four of the subjects in the
control group could not return to the hospital to repeat their measures so the PI met them at a location outside of the hospital to complete the measures. Two of the parents requested that the PI come to their home to repeat the measures. One parent requested that the PI meet her in a city park to repeat the measures and another parent requested that the PI come to her place of employment (a pizza parlor) to meet her child after school hours to complete the measures.

Description of Intervention

Open Airways for Schools was developed by researchers at Columbia University in conjunction with the American Lung Association. The program consists of role-play for new skill rehearsal, storytelling to increase problem solving skills, games that reinforce decision making, artistic activities to encourage expression of personal feelings that pertain to asthma and physical activity to reinforce symptom management skills.

While there are several asthma education curriculums available, this program was selected because it’s structured and standardized curriculum. It has been used in several pediatric populations and is highly effective with urban school children. The Open Airways for Schools program provides standardized teaching scripts for each session and handouts. While the program’s efficacy has been demonstrated among various groups of children, it was designed for use with children between the ages of 8 and 12 years of age. The program is a nationally recognized pediatric asthma education
program sponsored by the American Lung Association. The program purports to be highly effective in imparting asthma management skills to young school aged children, increasing self efficacy regarding asthma management and improving the overall quality of life for children with asthma (Evans et al, 2001; American Lung Association, 1992; Evans et al, 1987; Kaplan, 1986). These claims complement the previously mentioned objectives of the AAAAI and those of health teaching. There is a formal training session for instructors to attend users thus decreasing teaching variability from group to group. The PI attended a two day training session that was offered by the New Jersey American Lung Association.

The Open Airways for Schools curriculum is based on Jean Piaget's theory of child development (American Lung Association, 2005). The curriculum was designed for children between the ages of eight and eleven. These children are in Piaget's "concrete operational" phase of development. Children in this developmental phase learn best by doing and have a great sense of accomplishment when they are able to start a task and successfully complete it (Evans et al, 2001). This hands-on style of learning is very similar to the principles of experiential learning. When learning is fun, interactive and contains an element of reinforcement, the learner retains more, thus increasing the likelihood of a behavior change (Pike, 1994). Open Airways for Schools consists of six, 45-minute educational sessions. Open Airways for Schools is designed to be delivered in a school environment as part of the
child’s regular school day. The intervention in this pilot study required parents to bring their child to the hospital for education. For the purpose of this pilot study, the curriculum was condensed to three one and a half to two hour sessions by combining sessions one and two, three and four, and five and six. Condensed versions of Open Airways have been shown to be equally effective as the full session (Ronchetti et al, 1997). Asthma Management in Minority Children also described asthma education research that was done with young children using a condensed version of Open Airways for Schools from the usual six sessions to four sessions (NIH, 1995). The PI felt that condensing the program was necessary to avoid large numbers of attrition in the intervention group. The sessions ran for three consecutive weeks. There was a short break half way through the session with time for bathroom break and stretching. Nut free snack and juice were served at each session.

The first session started with an icebreaker that led into a discussion of: “what is asthma?” sharing feelings about asthma and a deep breathing exercise. The children also learned about “warning signs of asthma.” There was a discussion regarding asthma self-management, and role-play of the management steps. At the end of the session, the children were given three handouts. The first was a review of “Belly Breathing” and the other two handouts were “My asthma warning signs…” and the “Asthma self-management plan.” Parent information was included about asthma medications that their child was taking.
Children also had an attendance card. Each time they come to a session they were given stickers to place on their attendance card. This was intended to increase the child's sense of involvement and provide positive reinforcement for coming to the session. The attendance card was maintained in a folder that was kept by the trainer.

The second session consisted of a discussion of: solving problems with medications, a story and discussion regarding the child's ability to determine the severity of asthma symptoms and a game that focused on determining the severity of asthma symptoms. There was also a detailed discussion on how to identify asthma triggers. After the discussion, the children were asked to participate in a role-play activity about how to talk with their parents about triggers and possible solutions. Take home material included the “five emergency signs”, “what is a peak flow meter” and a handout on common asthma triggers.

The third session was a thirty-minute puppet show designed to facilitate discussion regarding ways to stay active with asthma. Following the puppet show, children were asked to participate in a game of Simon Says to reinforce the concept that children with asthma can play and have fun. There was also a discussion on “deciding when to go to school” and “making up missed up work”. The children were asked to draw a picture that showed how they felt about themselves. Handouts on “tensing and relaxing” were sent
home for parents to review. The children received a “Certificates of Good Asthma Management”.

Incentives were provided for all study participants. Subjects in the intervention group had an opportunity to earn stickers for their “participation chart”. Subjects were given stickers to put on their chart each time they came to a session. All participants received a completion certificate that comes with the Open Airways for Asthma Program and a gym bag as a completion gift. Those in the control group also received a certificate of appreciation and a completion gym bag for taking part in the study.

Instruments

Several instruments were used to measure the variables for this pilot study. This section describes the content, structure and psychometrics of all the instrumentation. This information has also been summarized in table 3.1.

Pulmonary Function

Pulmonary function is a measure and degree of airway constriction. This is determined by one of two means; PEF or FEV₁. PEF can be measured with a small hand held device called a peak flow meter. While peak flow meters have found to be adequate measuring instruments, there exists a degree of variability between devices and the measures are affected by equipment and patient position and patient effort. FEV₁ provides information regarding the function of the large airways. It is the forced volume of air that a person can exhale in one second. It can be measured using a
hand held peak flow meter or a spirometry machine. FEF_{25-75} is a measure of the small airway function. While some argue that the consistent and reliable values are harder to reproduce, it provides important information regarding obstruction of the small airway. This is important for children because most children have the greatest amount of obstruction in the small airways due to edema. Therefore the value is useful to practitioners who want to measure control and efficacy of inhaled corticosteroid therapy (Lebecque, 1992). Spirometry machines provide measures that are more reliable because the machines are calibrated at least once a day and possibly more depending on the number of maneuvers performed. Spirometry also provided information regarding predicted values of normal. Many spirometry machines have built in visual incentives to encourage patients to give maximum effort. Machine position is not an issue because the machine is stationary and the patient either sits or stands to perform the maneuver.

The machine that was used for this study was the SpiroUSB. This is a portable PC-based spirometer manufactured by Micro Direct, Inc. The product has a digital volume transducer that interacts with software on a PC. This particular spirometry machine enables the user to compare and trend studies for subjects. This product was selected because it is portable, uses a friendly Windows based laptop, yields accurate data, has within subject trending capability, has visual incentives for children and it is able to be calibrated thus ensuring more accurate results because the device will be
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transported to and from the study site. This particular spirometer meets American Thoracic Society recommendations for accuracy and precision in measuring FVC, FEV₁, and peak expiratory flow under ambient conditions (Micro Medical, 2002).

Asthma Knowledge

The asthma knowledge test is a ten-item questionnaire that uses a multiple choice and true false format. The pre-test and post-test contain the same questions in the same format and order. The test is part of the Open Airways for Schools program and is used to assess asthma knowledge before and after program intervention. The test was graded in a traditional manner where each question was weighted ten points with a maximum score of 100%. Scores were not shared with subjects; they were told that completion of the test was only to find out what they knew about asthma and to find out if they learned anything new about asthma. The researcher decided on this approach because assessments in this format are highly associated with tests that are given in school to measure performance. It was felt that this testing format can cause increased anxiety or encourages cheating, therefore the tests were not graded with the subjects and scores were not shared. Subjects were given the test prior to the start of the first intervention (baseline) at the end of the intervention or three weeks after baseline and six weeks after baseline.

Pediatric Asthma Quality of Life Questionnaire (PAQLQ)
The PAQLQ is a 23-item disease-specific questionnaire designed for children between the ages of 7 and 12 years of age. It was developed by Juniper, O'Byrne, Guyatt, Ferrie, and King in 1996. The instrument can be self-administered or interviewer administered. There are three individualized questions that require the subject to identify his, "favorite" or "special", activities that are limited due to asthma. The subject is then asked at subsequent administrations how much he has been affected by the previously mentioned symptoms. The instrument is comprised of three domains: symptoms (10 items), activity limitations (5-items – 3 are individualized), and emotional function (8 items). The subject uses a 7-point Likert scale to score the instrument. All items are weighted equally. A mean score is calculated across all items within a domain. The overall score is the mean across all items. Subject burden for instrument completions is reported at 10 minutes. The test is written at a third-grade reading level.

Psychometric Studies

Instrument developers recruited 52 pediatric subjects between 7 and 17 years of age to participate in a 9-week single cohort study. Data was collected at weeks 1, 5 and 9. Patients were reported to have a wide range of asthma severity. The instrument was tested for both evaluative and discriminative properties. The instrument was examined in three age groups (7yr 0 mo-10yr 11mo; 11yr 0 mo – 14 yr 11mo; 15 yr 0 mo – 17 yr 11mo) to assess validity across all age ranges.
The instrument was assessed to determine its ability to detect within-subject changes using a paired *t*-test. The instrument was also examined to determine its ability to detect changes between groups in terms of changes in quality of life over a 4-week period using an unpaired *t*-test of the differences between the beginning and the end of the study period. The responsiveness index was calculated from the minimal importance difference in treatment score. Longitudinal construct validity was assessed by correlating within-subject changes in quality of life scores over a 4-week period with within-subject changes and indices of clinical asthma severity and generic quality of life.

When developers assessed whether patients had stayed the same or changed during each time interval they found that the patient’s symptom global rating of change agreed more closely with their clinical assessment (*k*=0.71) than their caregiver’s report (*k*=0.48). Developers found that the overall *k* suggested that children were able to perceive a change in their health status well. The youngest group had the poorest perception (7-10 years *k*=0.35; 11-14 years *k*=0.55; 15-17 years *k*=0.89).

Overall, the developers found that children had little difficulty understanding the PAQLQ. Some of the children had a problem with the concept of, “last week”. In those cases, the developers asked the parents to identify an activity from the prior week for the child to use as a point of reference.
This instrument was found to be very stable and reliable in the intended age groups. There was a high correlation between questionnaire scores and asthma control, beta-agonist use and the feeling thermometer. There was no correlation between FEV₁ results and the PAQLQ. The test is not a useful measure of lung function, but rather a very useful measure of quality of life as perceived by the pediatric subject. For consistency, the researcher or designated person will sit with the subject, read the questionnaire in a matter of fact tone, and ask the child to answer the questions.

**Childhood Asthma Control Test (CACT)**

The CACT is a seven-item caregiver assisted, child-completed instrument. The instrument was developed by GlaxoSmithKline. The CACT can be used with or without spirometry to assess pediatric asthma control in the home or clinical setting. The instrument was designed for use with children ages 4-11 years old. The instrument is comprised of seven items divided in two sections. The first four items are child reported and the other 3 are caregiver reported. Items are reported using a Likert scale for the child to complete. Descriptive terms such as “very bad” are assigned a numeric value between 0 and 3 and a corresponding face. The second section is a three-item questionnaire for parents. The questions are temporal and responses are assigned a numeric value between zero and five. Scores can
range between 0 and 27. Higher scores indicate better control. A score of 19 or less indicates poor control (GlaxoSmithKline, 2005).

The CACT is an adaptation of the Asthma Control Test (ACT). The ACT is patient-based instrument for identifying patients with poorly controlled asthma. Psychometric information was reported by Nathan et al (2004). Quality Metrics holds the patent for the instrument.

Initially the instrument consisted of 22-items that were scored on a Likert scale. Each item asked the patient to consider the last 4 weeks. Participants completed the 22-item survey during routine office visits. After the survey was completed, the participant’s FEV₁ was measured. During the visit the patient’s asthma was rated by a specialist using a 5-point Likert scale. The rating given by the specialist was based on the NHBLI goals of asthma therapy as determined by history, physical and FEV₁. Stepwise logistic regression was used to identify items with the greatest validity in discriminating between patients who differed in the specialist’s rating of asthma control. Once the items were selected, reliability was assessed using internal consistency methods and Cronbach’s alpha (0.83).

Five items were selected for the Asthma Control Test. Screening accuracy is determined by a sum of item scores. The score can range from 5 to 25. A higher the score indicates better asthma control. A cut score of 19 or less is indicative of poor asthma control.
Juniper et al (1999) also developed the Asthma Control Questionnaire for use with adults. The questionnaire was developed in much the same way as the ACT however instead of starting with 22 questions, they started with 10 items and the final product is a 6-item instrument that assesses asthma control. The questions selected for the Juniper instrument are similar to the 5-item CACT developed by U.S. asthma specialists.

Initially there was no reported psychometrics for the use of the CACT in children under the age of 12 so the author conducted a preliminary study to determine the appropriateness of the CACT for younger children. Just as with the CACT, the instrument was used with patients in an asthma specialty practice. Children between the ages of 7 and 12 (n=10) and their parents who came for routine appointments were asked to complete the CACT. After the instrument was completed the children performed lung function tests with a registered respiratory therapist. A board certified pediatric pulmonologist evaluated the child's asthma control based on physical exam and FEV\textsubscript{1}. At the end of the visit, the specialist's assessment was compared to the CACT completed by the patient and their parent. The specialist's assessment correlated closely with the report of the children. In most cases (n=8) parents differed from the report of the child.

All of the children had difficulty with the time reference of “the last 4 weeks”. Parents were asked to give an example of an activity that had occurred over the past month for the children. Seven of 10 children had
questions about what the numbers and corresponding words on the Likert scale meant (i.e. not controlled, poorly controlled, somewhat controlled, well controlled, completely controlled). The FACES Pain Rating Scale was added to the assessment to correspond to the numbers and the children were asked to “point to the face that is most like the way your asthma makes you feel.” When this was added, all of the children were able to reliably rate their level of asthma control.

The FACES Pain Rating Scale consists of six cartoon faces ranging from a smiling face for “no pain” to a tearful face for “worst pain”. The pain scale was validated and found reliable for children as young as 3 years of age (Wong & Baker, 1991). The smiling face corresponds to number 0 and the tearful face corresponds to number 6. When the CACT was modified, the tearful face was omitted leaving faces 1-5 to correspond with the Likert scale. The numbers on the Likert scale were reversed for use with FACES scale since one on the CACT corresponds to “not controlled at all” and five corresponds to “completely controlled.”

GlaxoSmithKline has recently published psychometrics for the Childhood Asthma Control Test for Children 4-11 years old. The CACT was validated with a sample of 340 children between the ages of 4 and 11 (GlaxoSmithKline, 2005). Validation was done in the same fashion this investigator used in the earlier preliminary study with similar results.
Researchers found that the instrument correctly classified a patient's level of asthma control in 75% of the cases (GlaxoSmithKline, 2005).

**Asthma Severity in Children**

The NHBLI guidelines were used to measure and classify asthma severity. This system is used by providers to determine level of asthma severity and appropriate treatment. The NAEPP Expert Panel conducted a systematic review of published literature to determine the criteria that is used to classify severity (NAEPP, 2002).

The Stepwise Approach outlined in Managing Asthma in Adults and Children Older than 5 Years of Age was used to determined asthma severity in children. Managing Asthma in Adults and Children Older than 5 Years of Age is a pocket guide for clinicians that was established by the National Heart, Lung and Blood Institute and updated in 2002. Patients can be classified by using subjective data, clinical data or a combination of both. Patients are assigned to the most severe classification in which any feature occurs. Subjective data includes the patient's report of the number symptoms he experienced during the day or night in a given week. Clinical findings include measures of peak expired flow (PEF), forced expiratory volume in 1 second (FEV₁) and PEF variability.

There are four classifications for asthma severity. The first is mild intermittent. This classification is consistent with subjective asthma symptoms that occur less than twice a week during the day or less than twice
a month at night. Clinical symptoms are a FEV₁ or PEF that are equal to or greater than 80 percent of predicted normal or less than 20 percent airway variability. Patients with mild persistent asthma report that they experience asthma symptoms during the day more than twice a week or more than two nights per week. PEF or FEV₁ are equal to or greater than 80 percent of predicted normal or more than 30 percent of airway variability. Moderate persistent asthma is consistent with a patient report of daily asthma symptoms, night symptoms that occur more than once a week, a PEF or FEV₁ that is between 60 and 80 percent of the individual's predicted normal or more than 30 percent variability. The classification of severe persistent asthma is made when the person experiences continual daily symptoms and frequent or nightly night symptoms or a PEF or FEV₁ that is equal to or less than 60 percent or more than 30 percent airway reversibility. Refer to Table 3.2.
STUDY ALGORITHM

Subjects Assessed
Eligibility Determined

Dismissed

Not Eligible

Eligible

Subjects Recruited and Consent Obtained

Complete Demographic Questionnaire

Randomized

Intervention Groups

Control Group

Baseline Assessments
- Spirometry
- Asthma Test
- PAQLQ
- CACT

Open Airways for Schools Program for 3 weeks

Weekly Phone Calls for 3 weeks as attention control

End of Study Party and Award Ceremony

Repeat Measures at end of intervention and 3 weeks post intervention
- Spirometry
- Asthma Test
- PAQLQ
- CACT
<table>
<thead>
<tr>
<th>Variable Measured</th>
<th>Instrument (Source)</th>
<th>Level of Data</th>
<th>Statistical Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary Function: $H_1$</td>
<td>FEV$<em>1$ and FEF$</em>{25-75}$</td>
<td>Interval</td>
<td>Generalized Estimating Equation</td>
</tr>
<tr>
<td>Asthma Knowledge: $H_2$</td>
<td>S: Spirometry</td>
<td></td>
<td>Repeated measures ANOVA</td>
</tr>
<tr>
<td>Quality of Life: $H_3$</td>
<td>Asthma Knowledge Test</td>
<td>Ordinal</td>
<td>Repeated measures ANOVA</td>
</tr>
<tr>
<td></td>
<td>Pediatric Asthma Quality of Life Questionnaire PAQLQ</td>
<td>Interval</td>
<td>Repeated measures ANOVA</td>
</tr>
<tr>
<td>Symptom Control: $H_4$</td>
<td>S: Juniper et. Al</td>
<td>Interval</td>
<td>Repeated measures ANOVA</td>
</tr>
<tr>
<td></td>
<td>Childhood Asthma Control Test for Children Ages 4-11 years.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>S: GlaxoSmithKline</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Table 3.2 Asthma Severity

<table>
<thead>
<tr>
<th>Asthma Severity</th>
<th>Symptoms: Day/Night</th>
<th>PEF or FEV₁/ Variability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Persistent</td>
<td>Continual / Frequent</td>
<td>PEF/FEV₁: Less than or equal to 60%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Variability: More than 30%</td>
</tr>
<tr>
<td>Moderate Persistent</td>
<td>Daily / More than 1 night/week</td>
<td>PEF/FEV₁: 60% - 80%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Variability: More than 30%</td>
</tr>
<tr>
<td>Mild Persistent</td>
<td>Day: More than twice a week, once a day or less</td>
<td>PEF/FEV₁: More than 80%</td>
</tr>
<tr>
<td></td>
<td>Night: Two or more nights a month</td>
<td>Variability: 20%-30%</td>
</tr>
<tr>
<td>Mild Intermittent</td>
<td>Day: Less than two days a week</td>
<td>PEF/FEV₁: More than 80%</td>
</tr>
<tr>
<td></td>
<td>Night: Less than two nights a month</td>
<td>Variability: Less than 20%</td>
</tr>
</tbody>
</table>

NAEPP 2007
Data Analysis

Data was entered by the author at the completion of each intervention session. SPSS version 17.0 was used to manage data. Descriptive statistics were applied to the sample and variables. Group comparisons were made to test the hypotheses. Repeated measures ANOVA and generalized estimating equations (GEE) were used to compare differences in group means. Reliability scores were calculated for the various instruments. Analysis and findings are presented in chapter four.

Threats to Validity

Validity refers to the believability of a study's results. In other words, validity addresses how precisely the study's results represent the phenomenon of interest. This is not an all or nothing issue.

Validity was considered in the pilot design in preparation for conducting an appropriately powered randomized controlled study in the future. Study findings represent four types of validity. They are: statistical conclusion validity (have the statistics been correctly chosen implemented and interpreted), construct validity (is the concept or construct more than, less than, equal to, or the same), internal validity (are the study findings a result of the intervention or is there another explanation for the findings?) and external validity (are the study findings applicable to others outside the sample and setting of the present study?) (Norwood, 2000).
It is very difficult to ensure that each of the forms of validity is protected during a single study. However, by anticipating potential threats one may be able to exert a certain level of control over the study, decrease the probability of error, and strengthen the study’s findings. If the researcher fails to exert adequate controls, the study may yield inaccurate findings that may be harmful to healthcare consumers (Norwood, 2002).

Potential threats to this study were: 1. Selection bias. This occurs when the researcher intentionally or unconsciously assigns individuals to either a control group or a treatment group based on a certain difference. The process of random assignment was used to avoid this issue.

2. Mortality or attrition refers to the loss of subjects from a study. This study employed an experimental design with an intervention that lasted for six weeks. The probability of subjects in the intervention group not completing the sessions or those in the control not returning for post-test measures was a real concern. A loss of subjects would have resulted in an adverse effect on the ability to make within group comparisons and the power of the study. Also, as the number of subjects decreases, the probability for Type II error (failing to detect a difference between groups when one actually exists) increases.

3. At times external events can occur during the course of the study that may influence the outcome. For example, subjects randomized to the control group may receive a block of instruction regarding asthma and self-
management as part of a health class or they may view a television program about the subject. This is known as history. History is very difficult to control. However, surveying asthma knowledge before and after and ascertaining if the subject has participated in any type of educational program was determined via the demographic survey. Subjects were asked if they had ever participated in an Open Airways program before.

4. **Instrumentation** refers to changes that may occur in the measurement instrument. The reliability of pulmonary function measures can vary due to poor performance technique, and machine/program variability. Therefore, in order to increase reliability of the tests, only a trained respiratory therapist or the primary investigator collected spirometry data. Findings were interpreted by the primary investigator and if necessary confirmed with a board-certified pediatric pulmonologist. Subjects had spirometry measured at the same location with the same equipment using similar technique. All subjects were required to wear nose clips and stand for both the pre and posttest measurements. The machine was calibrated according to manufacturer's specifications. In order to increase the reliability of the educational intervention, the primary investigator attended an Open Airways for Schools Training session before the start of the study intervention. All written instruments were administered uniformly in accordance with the developers specifications during the pretest and posttest period.
A phenomenon known as diffusion of treatment or imitation of treatment may occur when the research design involves two or more groups and the treatment involves information. Contamination of the control group may occur if the subjects in the treatment group share the information with the subjects in the control group resulting in a non-treatment group for comparison purposes. Diffusion poses a serious threat to internal validity and may necessitate dissolution of both groups and beginning the study anew. This can be extremely costly and time consuming. For the proposed study, the potential for diffusion would be more likely to occur if the intervention was conducted in a school setting with subjects from the same school being randomized. This may also occur if siblings are recruited and randomized to opposing groups. To decrease the probability of diffusion the primary investigator recruited subjects from multiple physician practices in a large urban area rather than a single school. In addition, the intervention was not held at a school, but rather at a convenient location for community members. There were no sibling volunteers for this study.

Threats to internal and external validity are real issues with any study however careful planning can offer increased control. For this study, the primary investigator measured baselines for: asthma severity, quality of life, symptom control, pulmonary function and medication use before the independent variable was introduced. This was done by conducting baseline measures prior to the start of the intervention/study period. Demographic
data was collected via a questionnaire before the independent variable was introduced. Doing so increased the investigator's ability to compare groups at the outset and to appropriately generalize findings. Norwood (2002) recommends collecting a thorough history of health status and medication and health resource usage if the dependent variable is a biophysical measure or wellness measure such as lung function and the CACT. This information was obtained via the demographic questionnaire.
CHAPTER FOUR

RESULTS

One of the main purposes of a pilot study is to assess the feasibility of conducting a larger study. The classic pilot study is not appropriate for conducting statistical analysis; however, for the purpose of this study hypothesis testing will be done to verify the data analysis plan and ultimately to demonstrate knowledge of research for the dissertation process. In this chapter results related to enrollment, instrumentation and conduct of the study, as well as hypothesis testing results are reported.

Sample Characteristics

The sample was comprised of school-age children between the ages of 8 and 12 years of age who lived in an urban environment and had moderate to severe persistent asthma as determined by the NIH guidelines for step-wise management of asthma (Table 4.1)

The proposed sample for this pilot study was 30 subjects. Thirty-two subjects were recruited. Seventeen subjects were randomized to the control group and 15 subjects were randomized to the intervention group. Two subjects were withdrawn by their parents due to transportation and scheduling issues. These subjects attended only one intervention session. Their data were not included for analysis therefore there were no missing data sets. All of the subjects were included in the pilot analysis.
The sample for analysis consisted of 17 subjects in the control group and 15 subjects in the intervention group. There were 14 females (46.7%) and 16 males (53.3%). The ages of the subjects ranged between eight and twelve years of age. The mean age of subjects was nine years. Twenty-five (83%) of the subjects reported they were African American, three (10%) were Hispanic, and two (6%) were Caucasian one (3%). Subjects’ race/ethnic groups were significantly different with predominantly more African American children in the study ($x^2=54.8$(df 3), $p=<.0001$).

Subjects’ grades ranged between second and seventh grade and the mean was third grade. Length of asthma diagnosis as reported by the subjects’ parents ranged from three to twelve years with a mean length of diagnosis of six- and -a-half years. Sixteen subjects (53%) reported that they had received some type of asthma education prior to the study and 14 (47%) had not. Of those who had reported receiving asthma education prior to study participation, 11 (69%) received education from a parent or guardian, three (19%) reported receiving education from a nurse practitioner and two (12%) reported receiving asthma education from a doctor.

All of the subjects were insured. Eight (27%) subjects reported having private insurance and 22 (73%) were insured by a New Jersey Medicaid plan. Twenty-nine parents (96%) reported that their children had a medical home. One parent reported that their child did not have a medical home. Twenty-five (83%) subjects were taken to their doctor’s offices for management of
asthma and other health complaints. One (3%) subject received care at a
school based clinic and three (10%) parents reported that they used the
emergency department exclusively for management of asthma and other
health complaints.

All of the subjects had either moderate persistent or severe persistent asthma
as determined by the 2007 NHLBI guidelines. Twenty four (80%) of the
subjects had moderate persistent asthma and 6 (20%) had severe persistent
asthma. Years since diagnosis did not differ between groups (t=-1.13, df 28,
p=0.27).

Six (20%) of the subjects reported that they only used bronchodilators
to control their asthma. Twenty subjects (67%) reported using inhaled
corticosteroids to control their asthma. Sixteen (53%) of the subjects reported
using inhaled corticosteroids and a montelukast inhibitor to control asthma.
Two (6%) of the subjects reported using oral steroids in addition to their
inhaled steroids and four (13%) of the subjects were not sure of what their
medication regimen consisted. Twelve (40%) subjects in the control group
reported that they were exposed to at least one environmental trigger. Eleven
(37%) subjects in the intervention group reported that they were exposed to at
least one trigger. Twenty-four of the subject (80%) reported that they were
exposed to tobacco smoke, six (20%) denied tobacco smoke exposure.
### Table 4.1
Sample Characteristics

<table>
<thead>
<tr>
<th>Age</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Mean</th>
<th>Percent</th>
<th>Group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>8</td>
<td>12</td>
<td>9</td>
<td>-</td>
<td><em>t</em> = .93, df 28, <em>p</em> = 0.36</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>8</td>
<td>12</td>
<td>8.9</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>8</td>
<td>12</td>
<td>9.4</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>14</td>
<td>-</td>
<td>-</td>
<td>46.7</td>
<td><em>x</em>^2^ = 0.13 (df 1), <em>p</em> = .72</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>8</td>
<td>-</td>
<td>-</td>
<td>47.1</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
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<td>-</td>
<td>-</td>
<td>46.2</td>
<td></td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>16</td>
<td>-</td>
<td>-</td>
<td>53.3</td>
<td></td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>9</td>
<td>-</td>
<td>-</td>
<td>52.9</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>53.8</td>
<td></td>
</tr>
<tr>
<td><strong>Grade</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2^nd</td>
<td>7^th</td>
<td>3^rd</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>2^nd</td>
<td>7^th</td>
<td>3^rd</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>2^nd</td>
<td>6^th</td>
<td>3rd</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td><strong>Years with Asthma</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3</td>
<td>12</td>
<td>6.9</td>
<td>-</td>
<td><em>t</em> = -1.13, df 28, <em>p</em> = 0.27</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>3</td>
<td>12</td>
<td>6.5</td>
<td>-</td>
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</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>3</td>
<td>12</td>
<td>7.5</td>
<td>-</td>
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</table>

*n* = 30 Control n = 17 Intervention n = 13
Table 4.2
Race

<table>
<thead>
<tr>
<th>Race</th>
<th>Number</th>
<th>Percent</th>
<th>Group Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
<td></td>
</tr>
<tr>
<td>Manitoba Poles</td>
<td>25</td>
<td>83</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>12</td>
<td>71</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>13</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>6</td>
<td>$\chi^2=54.8$ (df 3), $p&lt;.0001$</td>
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<tr>
<td>Caucasian</td>
<td>2</td>
<td>6</td>
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<tr>
<td>Control</td>
<td>2</td>
<td>6</td>
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</tr>
<tr>
<td>Intervention</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>3</td>
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<tr>
<td>Control</td>
<td>3</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Sample n=30</td>
<td>Control n=17</td>
<td>Intervention n=13</td>
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Table 4.2 (continued)
Source of Asthma Education

<table>
<thead>
<tr>
<th>Asthma Education Source</th>
<th>Total</th>
<th>Control</th>
<th>Intervention</th>
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</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Nurse Practitioner</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Parent/Guardian</td>
<td>11</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>No Prior Education</td>
<td>14</td>
<td>7</td>
<td>7</td>
</tr>
</tbody>
</table>

Sample n=30    Control n=17    Intervention n=13
Table 4.3
Source of Medical Care

<table>
<thead>
<tr>
<th>Insurance</th>
<th>Number</th>
<th>Percent</th>
</tr>
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<tbody>
<tr>
<td><strong>Private</strong></td>
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<td></td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>27</td>
</tr>
<tr>
<td>Control</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td>Intervention</td>
<td>5</td>
<td>39</td>
</tr>
<tr>
<td><strong>NJ Medicaid</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>22</td>
<td>73</td>
</tr>
<tr>
<td>Control</td>
<td>14</td>
<td>82</td>
</tr>
<tr>
<td>Intervention</td>
<td>8</td>
<td>62</td>
</tr>
<tr>
<td><strong>Medical Home</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Doctor's Office</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>25</td>
<td>83</td>
</tr>
<tr>
<td>Intervention</td>
<td>14</td>
<td>82</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>92</td>
</tr>
<tr>
<td><strong>School Based Clinic</strong></td>
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<td></td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Control</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Intervention</td>
<td>0</td>
<td>0</td>
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</table>

Sample n=30 Control n=17 Intervention n=13
Table 4.3 (Continued)

<table>
<thead>
<tr>
<th>Emergency Department</th>
<th>Number</th>
<th>Percent</th>
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</thead>
<tbody>
<tr>
<td>Total</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>Control</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>Intervention</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td><strong>Asthma Severity</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>Moderate Persistent</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>80</td>
</tr>
<tr>
<td>Control</td>
<td>15</td>
<td>88</td>
</tr>
<tr>
<td>Intervention</td>
<td>9</td>
<td>69</td>
</tr>
<tr>
<td><strong>Severe Persistent</strong></td>
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<td></td>
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<tr>
<td>Total</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>Control</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>Intervention</td>
<td>4</td>
<td>31</td>
</tr>
<tr>
<td><strong>Tobacco Exposure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>(Singly or with other risks)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>80</td>
</tr>
<tr>
<td>Control</td>
<td>12</td>
<td>71</td>
</tr>
<tr>
<td>Intervention</td>
<td>12</td>
<td>92</td>
</tr>
</tbody>
</table>

Sample n=30  Control n=17  Intervention n=13
Table 4.4
Medication Use

<table>
<thead>
<tr>
<th>Asthma Medication</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bronchodilator Only</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>Control</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td>Intervention</td>
<td>3</td>
<td>23</td>
</tr>
<tr>
<td><strong>Inhaled Corticosteroids only</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Control</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>Intervention</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Bronchodilator and Corticosteroid</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>Control</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Intervention</td>
<td>2</td>
<td>15</td>
</tr>
</tbody>
</table>

Sample n=30  Control n=17  Intervention n=13
<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Corticosteroids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Bronchodilator</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and Montelukast Inhibitor</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>13</td>
<td>46</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>7</td>
<td>12</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td><strong>Not Sure</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Sample n=30</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Control n=17</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention n=13</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Pulmonary Function

H₁: Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the Open Airways Asthma education program will experience improved pulmonary function when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual provider asthma care.

Before testing the hypothesis the distribution of data for pulmonary function was analyzed. Findings are summarized in the table 4.5. The range of scores for FEV₁ and FEF₁₂₅₋₇₅ varied widely in both groups. Minimum scores for FEV₁ (measure of large airway function) in the control group ranged from 39% to 50% predicted over times one thru three. Maximum scores for FEV₁ ranged from 154% to 160% of predicted normal over times one thru three. Minimum scores for FEV₁ in the intervention group ranged from 30% to 54% predicted over times one thru three. Maximum scores for FEV₁ in the intervention group ranged from 114% to 132% of predicted normal over times one thru three. Minimum scores for FEF₁₂₅₋₇₅ (measure of small airway function) in the control group ranged from 9% to 24% predicted over times one thru three. Maximum scores for FEF₁₂₅₋₇₅ ranged from 121% to 138% of predicted normal over times one thru three. Minimum scores for FEF₁₂₅₋₇₅ in the intervention group ranged from 16% to 26% predicted over times one thru three. Maximum scores for FEF₁₂₅₋₇₅ ranged from 89% to 103%
of predicted normal over times one thru three. A test for skewness revealed that the ranges for both groups were skewed. Skewness for the control group was slightly negative and for the intervention group had a slight positive skew. Histograms of data were visually inspected and also demonstrated this pattern.
### Table 4.5
#### Pulmonary Function

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Minimum % Predicted</th>
<th>Maximum % Predicted</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Control</strong></td>
<td></td>
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<tr>
<td>FEV₁ T1</td>
<td>17</td>
<td>39</td>
<td>154</td>
<td>84.29</td>
<td>23.856</td>
</tr>
<tr>
<td>FEV₁ T2</td>
<td>17</td>
<td>39</td>
<td>150</td>
<td>83.53</td>
<td>25.326</td>
</tr>
<tr>
<td>FEV₁ T3</td>
<td>17</td>
<td>50</td>
<td>160</td>
<td>90.65</td>
<td>25.397</td>
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<tr>
<td><strong>Intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEV₁ T1</td>
<td>13</td>
<td>30</td>
<td>114</td>
<td>81.23</td>
<td>22.800</td>
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<tr>
<td>FEV₁ T2</td>
<td>13</td>
<td>45</td>
<td>132</td>
<td>85.85</td>
<td>25.478</td>
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<tr>
<td>FEV₁ T3</td>
<td>13</td>
<td>54</td>
<td>117</td>
<td>85.85</td>
<td>21.286</td>
</tr>
<tr>
<td><strong>Control</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEF₂₅-₇₅ T1</td>
<td>17</td>
<td>9</td>
<td>126</td>
<td>68.47</td>
<td>34.229</td>
</tr>
<tr>
<td>FEF₂₅-₇₅ T2</td>
<td>17</td>
<td>12</td>
<td>121</td>
<td>64.53</td>
<td>32.659</td>
</tr>
<tr>
<td>FEF₂₅-₇₅ T3</td>
<td>17</td>
<td>24</td>
<td>138</td>
<td>67.18</td>
<td>30.365</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FEF₂₅-₇₅ T1</td>
<td>13</td>
<td>24</td>
<td>89</td>
<td>62.46</td>
<td>23.525</td>
</tr>
<tr>
<td>FEF₂₅-₇₅ T2</td>
<td>13</td>
<td>16</td>
<td>103</td>
<td>68.77</td>
<td>26.230</td>
</tr>
<tr>
<td>FEF₂₅-₇₅ T3</td>
<td>13</td>
<td>26</td>
<td>98</td>
<td>60.85</td>
<td>23.832</td>
</tr>
</tbody>
</table>
To test this hypothesis, subjects from the intervention and control groups were asked to complete spirometry testing at three different time points. The first was at enrollment, the second was after the education intervention (three weeks later) and six weeks after the initial test. Spirometry is a non-invasive test that requires the subject to exhale forcefully into a machine (spirometer). The subject's results are calculated using a set of norms that are determined by race, age, height and weight. Normal values for FEV₁ and FEV₂₅-₇₅ (measures of large and small airways respectively) are 80% or better. Values less than 80% indicate abnormal pulmonary function.

Chi Square was calculated to determine if there was a difference between baseline FEV₁ and FEF₂₅₋₇₅ that were within normal ranges versus abnormal at the beginning of the study. An analysis of the data revealed that there was no difference in normal/abnormal proportions of baseline FEV₁ and FEF₂₅₋₇₅ between the groups at the beginning of the study (Pearson’s Chi Square = .880 for FEV₁ and .638 for FEF₂₅₋₇₅). Lung function measures were also analyzed as continuous data. A T-test was run to ascertain if there was a change in FEV₁ and FEF₂₅₋₇₅ scores between baseline and T3 within groups and between groups. There was no statistically significant change noted in scores within groups or between groups. Physiologically there would not be anticipated changes in lung function by time 2. Nevertheless, a generalized estimating equation (GEE) was calculated to account for the repeated
measures of spirometry over time. An analysis of the data using GEE found that for FEV₁ and FEF<sub>25-75</sub> scores there was no significant difference over time between groups (p=.86 and .79 respectively).

**Asthma Knowledge**

Asthma knowledge was assessed via the Asthma Knowledge Test, a ten-item questionnaire used in the Open Airways for Schools program. Subjects in this pilot study demonstrated great variability in scores at each administration. Scores for both groups ranged from 20% correct to 100. The median score for both groups at baseline was 55%, T2 was 70% and T3 was 65%. A test of skewness was done and scores for both groups at all data points were negatively skewed. The median score for the control group was 50% at baseline, T2 and T3. The intervention group had escalating median scores. Median score at baseline was 70%, T2 was 80% and T3 was 90%. Subjects in the intervention group demonstrated greater asthma knowledge at baseline as evidenced by higher median test scores at baseline.

The questionnaire is part of the Open Airways for Schools toolkit and has been used widely. However no published validation studies (item analysis) for the instrument are available. Because the instrument has so few questions on any one topic and tests a wide range of knowledge, reliability analysis for internal consistency would not be appropriate and so was not calculated for this sample. Subjects did not appear to have a problem with
the instrument. They were able to read the questions independently and answer without assistance.

**Hypothesis testing for knowledge test**

H$_2$: Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the Open Airways Asthma education program will demonstrate improved asthma knowledge when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual provider asthma care.

To test this hypothesis subjects were asked to complete the Asthma Knowledge test at baseline, after the intervention or three weeks after baseline (T2), and three weeks after T2 or six weeks after baseline (T3). Data analysis was done with repeated measures analysis of variance to test for differences across the three time periods and between groups. This is a mixed design which is comprised of between subject and within subject measures. Within subject factors for testing at times one through three were analyzed for the control group (n=17) and the intervention group (n=13). Table 4. 6 summarizes the descriptive statistics for the Asthma Knowledge test across these three times.
Table 4.6
Asthma Knowledge

<table>
<thead>
<tr>
<th>Test</th>
<th>Group</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score on Pre Test</td>
<td>Control</td>
<td>50.59</td>
<td>21.929</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>61.54</td>
<td>18.640</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>55.33</td>
<td>20.965</td>
<td>30</td>
</tr>
<tr>
<td>Score on 1st Post Test</td>
<td>Control</td>
<td>53.53</td>
<td>20.292</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>83.85</td>
<td>10.439</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>66.67</td>
<td>22.489</td>
<td>30</td>
</tr>
<tr>
<td>Score on 2nd Post Test</td>
<td>Control</td>
<td>50.59</td>
<td>17.489</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>85.38</td>
<td>12.659</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>65.67</td>
<td>23.295</td>
<td>30</td>
</tr>
</tbody>
</table>
A General Linear Model repeated measures Analysis of Variance was calculated to account for data collected across the three time periods and to determine within subjects and between groups differences. Mauchly’s test of sphericity was used to test whether the assumption of compound symmetry was met. This assumption is critical in order to use the repeated measures analysis of variance. The test was significant, therefore sphericity cannot be assumed. In such cases a multivariate test or a univariate test with an Epsilon Correction can be used (Munro, 2001). A test of within-subjects effects was used with the Epsilon correction made through the Greenhouse-Geisser and Lower-bound results. Both of these approaches are considered highly conservative. The Greenhouse-Geisser result is more appropriate for small samples and the Lower-bound provides the most conservative result of all the tests (Munro, 2001). Results are summarized in table 4.7. Table 4.8 summarizes the results of tests of between-subjects effects. The test revealed a significant difference between the control and intervention group. The F value was 19.028 with a significance level of .000.
Table 4.7

<table>
<thead>
<tr>
<th>Source</th>
<th>Type III Sum of Squares</th>
<th>df</th>
<th>Mean</th>
<th>F</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Knowledge Test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sphericity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assumed</td>
<td>2966.586</td>
<td>2</td>
<td>1483.293</td>
<td>14.647</td>
<td>.000</td>
</tr>
<tr>
<td>Greenhouse-Geisser</td>
<td>2966.586</td>
<td>1.573</td>
<td>1885.922</td>
<td>14.647</td>
<td>.000</td>
</tr>
<tr>
<td>Geisser</td>
<td>2966.586</td>
<td>1.710</td>
<td>1734.833</td>
<td>14.647</td>
<td>.000</td>
</tr>
<tr>
<td>Huynh-Feldt</td>
<td>2966.586</td>
<td>1.000</td>
<td>2966.586</td>
<td>14.647</td>
<td>.000</td>
</tr>
<tr>
<td>Lower-bound</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Table 4.8

Asthma Knowledge Tests of Between Subject Effects

<table>
<thead>
<tr>
<th>Source</th>
<th>Type III Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Significance</th>
<th>Partial Eta Squared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>364873.610</td>
<td>1</td>
<td>364873.610</td>
<td>488.702</td>
<td>.000</td>
<td>.946</td>
</tr>
<tr>
<td>Randomized</td>
<td>14206.943</td>
<td>1</td>
<td>14206.943</td>
<td>19.028</td>
<td>.000</td>
<td>.405</td>
</tr>
<tr>
<td>Error</td>
<td>20905.279</td>
<td>28</td>
<td>746.617</td>
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</tr>
</tbody>
</table>
Therefore H₂: Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the Open Airways Asthma education program will demonstrate improved asthma knowledge when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual provider asthma care is supported.

Quality of Life

Quality of life was assessed via the administration of the Pediatric Quality of Life Questionnaire (PAQLQ) at baseline, after the intervention or three weeks after baseline (T2), and three weeks after T2 or six weeks after baseline (T3). The PAQL is a 23-item questionnaire that is scored on a 7-point Likert scale by the subject. Median PAQLQ scores for both groups ranged from 100 to 153. The median score for both groups at baseline was 116, T2 was 106 and T3 was 142. The median score for the control group was 114 at baseline, T2 was 110 and T3 was 128. The intervention group had escalating median scores. Median score at baseline was 124, T2 was 147 and T3 was 153. Subjects in the intervention group had higher quality of life scores at baseline. Table 4.9 summarizes the descriptive statistics for the instrument across these three times.

Reliability scores were calculated for the PAQLQ. The Cronbach’s alpha was 0.952 indicating strong reliability. The PAQLQ has been used widely and has demonstrated consistent reliability. Cinta et al (2005) found a
reliability of 0.905 in children ages seven to seventeen years of age who used the PAQLQ. Reliability scores were also calculated for each of the sub domains, activity, symptoms and emotional of the PAQLQ. Cronbach’s Alpha scores were: activity .880, symptom .898, and emotional .897.

Hypothesis Testing

H₃: Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the Open Airways Asthma education program will report improved quality of life when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual asthma care.

To test this hypothesis the Pediatric Asthma Quality of Life (PAQL) survey was administered to all subjects at the beginning of the study intervention (baseline), three weeks later at the end of the intervention T2 and six weeks after baseline T3. The PAQL is 23-item survey comprised of three sub-parts or domains that measure activity limitations, asthma symptoms and emotional function. Subjects review a statement or question and then answer using a seven-point Likert scale. The individual items within the PAQL are weighted equally and the questionnaire is analyzed from the subject’s recorded scores. The results are expressed as mean scores for each item of each domain. Overall quality of life is estimated from the mean score of the total items (Juniper, 2001).
Repeated measures analysis of variance was used to test for differences across the three time periods and between groups. Within subject factors for testing at times one through three were analyzed for the control group (n=17) and the intervention group (n=13). Mauchly's test of sphericity was used to test whether the assumption of compound symmetry was met. The test was significant, therefore the assumption of compound symmetry was met. A test of within-subjects effects was used with the Epsilon correction made through the conservative Greenhouse-Geisser and Lower-bound results. The results of the Epsilon correction are summarized in table 4.10. Improvement over time was significant. Table 4.11 summarizes the results of tests of between-subjects effects. The test failed to reveal a significant difference between the control and intervention group. The F value was 2.708 with a significance level of .111.
Table 4.9
PAQLQ

<table>
<thead>
<tr>
<th>Sum Score</th>
<th>Group</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
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<tr>
<td>PAQLQ Baseline</td>
<td>Control</td>
<td>104.3529</td>
<td>36.80513</td>
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<td></td>
<td>Intervention</td>
<td>116.5385</td>
<td>35.59638</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>109.6333</td>
<td>36.18581</td>
<td>30</td>
</tr>
<tr>
<td>PAQLQ T2</td>
<td>Control</td>
<td>108.1765</td>
<td>39.65040</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>127.5835</td>
<td>30.25066</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>116.5667</td>
<td>36.62361</td>
<td>30</td>
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<tr>
<td>PAQLQ T33</td>
<td>Control</td>
<td>115.17675</td>
<td>39.44337</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>141.6154</td>
<td>23.13201</td>
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<tr>
<td></td>
<td>Total</td>
<td>126.6333</td>
<td>35.45904</td>
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Table 4.10
PAQLQ Epsilon Correction

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<th>F</th>
<th>Significance</th>
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</thead>
<tbody>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>PAQLQ</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sphericity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assumed</td>
<td>300.517</td>
<td>2</td>
<td>150.258</td>
<td>9.705</td>
<td>.000</td>
</tr>
<tr>
<td>Greenhouse-Geisser</td>
<td>300.517</td>
<td>1.781</td>
<td>168.700</td>
<td>9.705</td>
<td>.000</td>
</tr>
<tr>
<td>Geisser</td>
<td>300.517</td>
<td>1.962</td>
<td>153.169</td>
<td>9.705</td>
<td>.000</td>
</tr>
<tr>
<td>Huynh-Feldt</td>
<td>300.517</td>
<td>1.000</td>
<td>300.517</td>
<td>9.705</td>
<td>.004</td>
</tr>
<tr>
<td><strong>Lower-bound</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4.11
PAQLQ Tests of Between Subject Effects

<table>
<thead>
<tr>
<th>Source</th>
<th>Type III Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Significance</th>
<th>Partial Eta Squared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>61118.047</td>
<td>1</td>
<td>61118.047</td>
<td>332.614</td>
<td>.000</td>
<td>.922</td>
</tr>
<tr>
<td>Randomized</td>
<td>497.603</td>
<td>1</td>
<td>497.603</td>
<td>2.708</td>
<td>.111</td>
<td>.088</td>
</tr>
<tr>
<td>Error</td>
<td>5145.020</td>
<td>28</td>
<td>183.751</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Repeated measures ANOVA was also run for each of the sub domains of the PAQLQ. Mauchly's test of sphericity was conducted for each of the sub domains to test whether the assumption of compound symmetry was met. The test was not significant for any of the sub domains, activity, symptoms or emotional, therefore the assumption of compound symmetry was met. There was no significant difference between groups for the PAQLQ activity sub domain F value 2.708, \( p=.111 \). There was no significant difference between groups for PAQLQ symptom domain F value 1.567, \( p=.221 \). There was no significant difference between groups for the PAQLQ emotional domain F value 3.454 \( p=.074 \). The between groups differences for activity approached trend level for emotional domain was at trend level.

Therefore \( H_3 \): Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the Open Airways Asthma education program will report improved quality of life when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual asthma care was not supported. There was no significance between groups found for any of the sub domains, or in summary there was no change at any level for quality of life.
Symptom Control

Symptom control was assessed by asking the subjects to complete the Child Asthma Control Test (CACT) at baseline, after the intervention or three weeks after baseline (T2), and three weeks after T2 or six weeks after baseline (T3). The CACT is a seven-item Likert scale questionnaire that is completed by both the child and the parent. Possible scores range from 0 to 27. A score of 19 or less indicates the subject’s asthma is not controlled well. A review of the descriptive statistics for the CACT revealed that the mean scores for both groups were well below 19 at baseline, T2 and T3. There was a pattern of improvement noted for the both groups with consistently increasing mean scores over time. Table 4.12 is a summary of the descriptive results.
Table 4.12
CACT

<table>
<thead>
<tr>
<th>Sum Score</th>
<th>Group</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>CACT Baseline</td>
<td>Control</td>
<td>7.71</td>
<td>2.710</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>7.77</td>
<td>2.713</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>7.73</td>
<td>2.664</td>
<td>30</td>
</tr>
<tr>
<td>CACT T2</td>
<td>Control</td>
<td>7.24</td>
<td>2.840</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>8.15</td>
<td>2.444</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>7.63</td>
<td>2.671</td>
<td>30</td>
</tr>
<tr>
<td>CACT T3</td>
<td>Control</td>
<td>8.18</td>
<td>2.811</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Intervention</td>
<td>9.62</td>
<td>1.895</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>8.80</td>
<td>2.524</td>
<td>30</td>
</tr>
</tbody>
</table>
Hypothesis Testing

To test this hypothesis the CACT was administered to all subjects at the beginning of the study intervention (baseline), three weeks later at the end of the intervention T2 and six weeks after baseline T3. The subjects were asked to read a short statement regarding asthma and then circle a numerical score that corresponds to a cartoon face that describes their current perception of asthma symptom. The instrument was developed by GlaxoSmithKline who granted permission to use the instrument however validation studies for the instrument have not been published. Reliability statistics were computed for this pilot project and the Cronbach's Alpha is .809.

Repeated measures analysis of variance was used to test for differences across the three time periods and between groups. Mauchly's test of sphericity was used to test whether the assumption of compound symmetry was met and the non significant value indicated this was the case. Therefore, correction scores are not required and the univariate statistics are consulted. Table 4.13 summarizes the results of tests of between-subjects effects. The test failed to reveal a significant difference between the control and intervention group. The F value was 1.001, $p=.326$.

Therefore $H_4$: Children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and participate in the Open Airways Asthma education program will report less symptom
exacerbation when compared to children ages 8 to 12 years of age with moderate to severe persistent asthma who live in an urban environment and receive usual provider asthma care was not supported.
Table 4.11
CACT Test of Between Subject Effects

<table>
<thead>
<tr>
<th>Source</th>
<th>Type III Sum of Squares</th>
<th>df</th>
<th>Mean Square</th>
<th>F</th>
<th>Significance</th>
<th>Partial Eta Squared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>5813.324</td>
<td>1</td>
<td>5813.324</td>
<td>404.574</td>
<td>.000</td>
<td>.935</td>
</tr>
<tr>
<td>Randomized</td>
<td>14.390</td>
<td>1</td>
<td>14.390</td>
<td>1.001</td>
<td>.326</td>
<td>.035</td>
</tr>
<tr>
<td>Error</td>
<td>402.332</td>
<td>28</td>
<td>14.396</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Pulmonary Function

Findings from this pilot study suggest that relative to usual care, participation in a structured asthma education program like Open Airways for Schools was not associated with improved pulmonary function in terms of FEV₁ and FEF₂₅-₇₅. During the six weeks of study participation, there was no statistically significant change in pulmonary function between groups across the data collection time periods. This is not surprising and may be attributed to any one of several findings during this pilot phase. The most important of these may be the severity of the subjects' disease. The subjects enrolled in this study had asthma that was classified as moderate to severe persistent meaning they had more significant disease than someone with mild intermittent or mild persistent asthma. This is evidenced by the low mean scores on the CACT and the abnormal FEV₁ and FEF₂₅-₇₅ measures. The majority of the subjects were recruited from the pediatric emergency department and the inpatient general pediatric and pediatric intensive care units during or shortly after symptom exacerbation. Thus subjects entered the study with significant airway obstruction due to their recent exacerbation. Given the pathophysiology of asthma and what happens during an asthma exacerbation, there is more airway edema and obstruction, especially in the smaller airways. The edema and obstruction take as much as six weeks to
fully resolve and is reflected in FEV$_1$ and FEV$_{25-75}$ values. Also statistically significant improvement in pulmonary function would in likelihood have taken longer than six weeks to manifest. This finding is consistent with the findings of Di Franco et al (2003), who found that four weeks after initial asthma exacerbation and treatment with one week of oral steroids, sputum eosinophilia (a measure of lower airway edema) remained high in patients who had more significant airway obstruction during asthma exacerbation. Additionally, subjects in this pilot study had poorly managed asthma for an average of 7 years. One must consider that perhaps the obstruction associated with their asthma had become less responsive to medication. It could also be that the obstruction is now “fixed”, as in airway remodeling, due to the chronic inflammation (The Merck Manual for Healthcare Professionals, 2009). Future studies would benefit from prolonged data measurement points.

Measuring pulmonary function at T2 (3 weeks after baseline) was not beneficial. From a clinical reference, improved airway function following an acute exacerbation may require at minimum 6 to 8 weeks to occur. Perhaps the addition of more data collection periods would be helpful especially with the repeated measures ANOVA analysis. Using a larger sample would also help ensure that a Type II error is avoided.

This pilot study was unfunded so the PI was the primary source of data collection. While the PI had some volunteer assistance from colleagues in
the respiratory department, the majority of the data was collected by the PI. Attention phone calls to the control group and the reminder phone calls to the intervention were also mostly done by the PI. A close examination of the data revealed that pulmonary function scores for FEV$_1$ and FEF$_{25-75}$ were slowly improving over time, but for both groups. There was an inevitable dispersion of treatment effect because of this. On several occasions the subjects were symptomatic and the PI mentioned to the subject and the parent that control or medication use was needed. On one occasion the PI measured spirometry for a control subject and FEV$_1$ and FEF$_{25-75}$ were less than 50% predicted (severe exacerbation) and the parent was directed to administer medication and take the child for treatment. Ethically there was no way to avoid this level of interaction with the control group. On other occasions the PI heard the subject coughing or wheezing during attention phone call and the issue was addressed. In the future the attention phone call should be dropped. While attrition is a big concern, attention could be achieved by the PI mailing a post card instructing the subject to call for a follow up appointment. This level of treatment dispersion could account for a failure to detect between groups differences. The control group's pulmonary function was improving right along with the intervention group making a statistically significant difference more difficult to detect.

Another possible explanation is that subjects may not have had appropriate medications (inhaled corticosteroids) on hand following their
recent exacerbation or they may not have been taking the medications appropriately. However there was no way to determine this because the information was not collected. Collecting information regarding medication use and omission at all data collection time intervals would be a recommended change to the current protocol.

Tobacco exposure is a major asthma irritant and trigger and 80% of the total subject population (71% control and 92% intervention) was exposed to tobacco either singly or in association with other risk factors such as: dust, roaches, rodents, mold or furred pets. A large number of the subjects in both groups were exposed to tobacco which is a major asthma trigger. Given this fact, even though the subjects in the intervention group received additional education and subjects in both groups reported taking their medications, airway obstruction likely persisted for some because the constant exposure to the smoke irritant of tobacco (Chilmoczyk et al (1993) and Gordon et al (2009).

**Asthma Knowledge**

Subjects in the intervention group demonstrated a statistically significant improvement in asthma knowledge score over the three measurement periods. Prior to the start of this pilot study 46% of the subjects reported receiving some type of asthma education. Of those who reported prior asthma education 31% reported receiving the education from a parent or guardian. While the content of education they received is unknown, this
finding is important. Open Airways for Schools focuses on educating school aged children with the hopes they will educate their parents by sharing information regarding what they learned in the classes (Evans, 2001). It is hard to know what parents or family members have told children about their asthma. While some may have given proper education regarding medication use and symptom recognition, others may have unknowingly imparted information that was inaccurate to say the least. In the process of educating the child either formally or informally, the parent shares their health belief regarding asthma. If a parent doesn’t believe that asthma is a serious condition that can be controlled with proper medication, lifestyle and environmental changes or controls then this can be passed on to the child making behavior change difficult. Even if the child accepts these principles if the parent doesn’t, then environmental change will be difficult to achieve. The PI feels that moving forward, a more dyadic approach to education may be beneficial. The intervention group will still receive the Open Airways curriculum, however the parents would be receive concurrent education regarding asthma pathophysiology, trigger identification and avoidance, and appropriate medication use. It would also be both interesting and useful to ascertain the content of the information that the parent taught the child. Therefore a protocol change for a larger RCT will be considered.

Orem’s Theory of Self Care may not be the best theory for this type of study. The theory purports that the subject will engage in self care behavior
that will result in improved health outcomes. In reality, the child is powerless to make major changes to their environment. They can’t make a parent stop smoking, move to a cleaner apartment, or fill medication prescriptions. They rely heavily on the adults in their lives to assist them. Perhaps moving to or incorporating Ajzen and Fishbein’s Theory of Reasoned Action/Planned Behavior or Becker’s Health Believe Model may be useful as the PI looks to modify the intervention to include concurrent parent asthma education. This finding regarding asthma knowledge supports the importance of repeated structured asthma education for patients who live with the disease. (Brown et al, 2004; NAEPP, 2007; Frederic, 2003; Marabini et al, 2002; Velsor-Freiedrich et al 2005 ). Compared to the intervention group, subjects in the control group demonstrated marginally increased asthma knowledge scores. This pilot study demonstrates that a structured asthma education program makes a meaningful difference in terms of increased asthma knowledge over a short period of time. Patients with increased knowledge of their disease condition are better able to manage their health in terms of appropriate use of medication and early symptom recognition, thereby decreasing the need for emergency care and hospitalization (Glasgow et al, 2003; Velsor-Freiedrich et al 2005; Cowie et al 1997 and Gibson et al 2000; Coffman et al, 2008). Implementation of a standardized asthma education program for children has the potential to result in decreased health care expenditures.
Quality of Life

Quality of life improved for both groups during the study period. However the improvement was not statistically significant between groups. The PAQLQ addresses symptoms, activity and emotion. All of these scores combine for an overall quality of life sum score. Treatment dispersion may have accounted for this because as the subjects in the control group received instruction regarding management symptom exacerbation, their symptoms would have decreased, they probably felt better and were a thus able quality of life may have been affected because they felt better therefore they were able to participate in more of their favorite activities. Quality of life is highly correlated with symptoms (Levy et al 2004; Moy et al, 2001; and NHLBI, 2007) the PAQL was administered at enrollment, three weeks later and then at the end of the study period (six weeks after the initial administration). As the subjects had improved symptoms and felt better, it stands to reason that their perception of quality of life would also improve. Yet, significantly more improvement occurred in the intervention group. This may be attributed to the intervention as subjects continued to learn about asthma care they had better utilization of asthma medications and were able to better manage their symptoms. It is clear that treatment positively impacted both groups. Moving forward the PI will need to change the protocol so that this is avoided. One suggestion for protocol modification would be to send reminder post cards to subjects in the control group regarding follow up. Also, other non-clinical
assistants could be trained in spirometry data collection. This way they will only collect the data and not instinctively analyze the results.

**Asthma Symptoms**

Subjects who were recruited into this study were experiencing or had recently had an acute asthma exacerbation. From the outset of the study subjects had poorly controlled asthma as demonstrated by very low mean scores on the CACT at baseline. While mean scores improved steadily for both groups, improvement never reached a level of statistical significance. This is not surprising given the fact that there wasn’t a statistically significant improvement in pulmonary function. Subjects may still have felt the effects of inflammation and obstruction following their exacerbations. Again, due to the severity of their disease more time may have been needed for them to feel better and thus report significantly improved symptoms. The fact that there wasn’t a statistically significant improvement in asthma symptoms may be explained by the fact that most of the subjects were recruited while they were recovering from an acute exacerbation and recovery is correlated with severity of symptoms. In other words, subjects who were sicker, meaning more significant airway edema and obstruction, may have taken longer to recover (The Merck Manual for Healthcare Professionals, 2009’ Di Franco et al, 2003).
**Methodological Implications**

Pilot studies are small studies that are conducted prior to larger studies. The purpose of the pilot is to test recruitment procedures and ensure that they are reasonable, assess the appropriateness and usefulness of instruments and to ensure the protocol works and doesn't need to be changed. The smaller pilot study also gives evidence regarding whether or not the effort and financial expenditures should be used for a larger study. This pilot study has provided the PI with a great deal of information that will be useful prior to embarking on a larger randomized clinical trial.

**Recruitment Measures**

Subjects for this pilot study were mostly recruited from one urban hospital center. A few of the subjects came from outside referrals. Many of the subjects were recruited by face-to-face interaction with a staff member or the PI. Large culturally and age appropriate posters were developed for this study. All recruitment material was IRB approved by both Columbia University and Newark Beth Israel Medical Center. The posters were placed around the hospital in areas where children frequent (pediatric ED, pediatric specialty clinic, pediatric clinic, hallways of the inpatient units). Flyers were also posted in the restrooms of these areas. The PI feels that while the posters were colorful, and fun, they were not effective. This may be in part because there is so much signage on the walls and throughout the corridors of the hospital and clinics that they posters were “visually lost”.
A tri-fold brochure was developed to personally hand to potential subjects and their parents and to distribute in waiting areas and during brief encounters. The PI and staff found these to be more helpful. During patient encounters in the ED, clinic, or in patient units, staff were encouraged to give potential subjects a brochure. The brochure was printed on brochure weight paper and contained a brief description of the study, a brief bio and contact information for the PI and a place for the subject or parent to write their contact information if they were interested. Subjects and their parents were able to complete the brochure at their convenience and fax, mail or return the brochure to a staff person. Brochures that were collected in the hospital were forwarded to the PI via interoffice mail. On some occasions staff would call the PI to come and pick up the brochure because they wanted to ensure that the information "didn't get lost."

Information regarding the study was presented during a pediatric grand rounds session and flyers were left for area pediatricians. The PI also called local pediatricians who routinely referred patients to the pulmonary clinic for asthma and asked them to identify potential patients. This was not very effective. Area pediatricians did not refer any of their patients for the study. Physician colleagues who worked with the PI regularly were helpful in handout brochures or alerting the PI to potential subjects. There was also a pediatric nurse practitioner at a local school based clinic that referred two patients for the study.
Information regarding was printed in the employee newsletter on several occasions. This was not a helpful source of recruitment for the study. The study was also listed on the hospital website. There were two contacts from this and they happened to be college students who were looking for a project to help with for the semester. No subjects were obtained from this source. The PI considered advertising in a local neighborhood paper, however the cost to submit an ad was cost prohibitive. Radio and television ads were not an option due to cost.

Moving forward the PI would consider utilizing the brochures along with a group of volunteers who would be able to approach patients in pharmacies, emergency departments and physician clinics and offices.

**Instruments**

Several instruments were used for this study. The portable spirometry unit to measure pulmonary function was extremely useful. It proved reliable and easy to use. The disposable filters are approximately $1.00 each which can potentially become expensive in a larger study with repeated measures. There are less expensive filters available however the PI opted to use a disposable filter that is small enough to filter tuberculosis and influenza bacteria and viruses. A larger study will require funding to cover the cost of these supplies.

PAQLQ is 23 items and does not contain any pictures. At first site it looks overwhelming because it's just words, numbers and boxes. At the first
administration the subjects complained when they first saw the instrument. They felt it was too long. For subsequent administrations the PI printed the instrument double-sided to decrease the number of pages the subjects had to handle. The complaining decreased. The instrument comes with a three column answer sheet to be used for T1, T2 and T3. The subjects can also write directly onto the questionnaire booklet. Even though the PI received some help with printing, it was felt that printing three booklets per subject would be a waste of resources. The answer sheet was used, but during the second administration the PI noticed that two of the subjects were just copying their answers from the previous column. The PI gave those subjects new forms to use for T2. One suggestion for future studies would be to space the columns in such a way that the form could be folded three times so that previously selected answers are obscured. This was actually done and proved to be quite useful. The PI could also “spelling paper” tablets for subjects to record answers or over subjects answer strips so that answers would be recorded on separate forms for each administration of the instrument.

The Asthma Knowledge test is a brief 10-item instrument that was very easy for the subjects to answer. It was well received by them. For future studies the PI would consider running an item-analysis to ensure that questions are worded appropriately and are actually testing the knowledge the researcher wants to measure.
The CACT was used to measure asthma control. This instrument requires both the child and the parent to complete the instrument. The PI observed that some parents wanted to prompt their child’s response. They would say things like, “Are you sure your asthma is that bad?” “You are coughing at night because I don’t hear you.” Parents were assured that the instrument wasn’t going to be “graded” and that the PI was most interested in the child’s perception of his or her asthma symptoms, however some parents were getting upset when their children indicated that they had frequent asthma symptoms. This may have been because the corresponding faces were “sad looking”. The exact cause of the agitation was unclear. During the course of the pilot study the PI discovered an instrument that was developed by Juniper to measure asthma control. The instrument is called the Asthma Control Questionnaire and consists of seven items. Six items are completed by the subject without parent involvement and the last item is a measure of FEV₁ that is completed by a staff person. This questionnaire doesn’t have corresponding faces, however it will be considered for future studies because there’s no parent involvement.

The PI would consider assessing medication use, health care resource utilization, and trigger exposure during the repeated measures. This can easily be done by asking the subjects answer the questions from the demographic form again. The entire form doesn’t need to be completed so to decrease confusion a new form would be created that would contain only
those questions that were pertinent. Subjects from both groups have taught the PI that too many words on plain paper can be overwhelming, even if the questions are brief.

**Study Protocol**

Prior to commencing with a full scale RCT the PI would make the following protocol amendments. 1) The measurement intervals would be lengthened to every six weeks to account for normal physiological changes that occur over time in the lung. After reviewing the data analysis, repeating measures every three weeks proved to be short of an interval to realize statistically significant differences between groups. This would require lengthening the study from six weeks to twelve weeks with four sets of measures. The first would be baseline then three weeks later at the end of the intervention (T2) (except for spirometry), six weeks after T2 (T3) and then six weeks after T3 (T4). 2) The intervention would become dyadic and include concurrent education of the parent or guardian. Concurrent education is suggested to decrease caregiver burden regarding transportation. The child participant would be in one room receiving Open Airways for Schools curriculum and the parent would be in another area receiving information regarding asthma pathophysiology (brief for laypersons), appropriate use of medications and devices and trigger identification and control to include referral to smoking cessation for those parents who desire to quit smoking. The completion stipend/prize would need to be a bit more substantial if
parents will be asked to attend with their children. Rewards would also need to be incremental to ensure that the subjects returned for all data measures. This will require some funding.

Implications for Practice

While a pilot, the findings of this study are promising because they suggest that a formal and established asthma education program may go beyond its purpose of increasing asthma knowledge. Asthma experts have long held that educating patients is an important part of asthma care (NHLBI, 2007; Otto et al, 2006; Turcios, 2000 and Velsor-Friedrich, 2005). These results demonstrate that children who participated in formal, small group, asthma education utilizing a structured format do fare better than their peers who received only the usual asthma education that is a standard of care in the physician's office. It is not clear how usual care is imparted in the physician's office, however when done properly asthma education takes time because materials and information need to be presented in small intervals and reinforced often (NHLBI, 2007). Doing so increases knowledge retention, thereby improving asthma health outcomes (Clark, 2002).

Studies have shown that many providers do not provide asthma education because they do not know how to, or are not confident providing asthma education (Cabana et al 2002). Others mistakenly believe that they will not be reimbursed for asthma education (National Asthma Education Certification Board, http://www.naecb.org/cbr/; Bodenheimer et al, 2004) or
they think that reimbursement for education is not worth the time spent (Bodenheimer, et al, 2004; Cabana & Meurerer, 2005) and still others complain that they don’t have the time to provide asthma education during visits (Holness et al, 2007). Without proper reimbursement, there is very little incentive for providers in a busy practice to spend the much needed time on in-depth asthma education (Bodenheimer et al 2004). Asthma education is reimbursed by insurers (NAECB, Cabana et al, 2005) and this information needs to be effectively disseminated. Hiring certified asthma educators to provide detailed asthma education may prove beneficial for the practices and the patients. Just as a certified diabetic educator is reimbursed at a higher rate for diabetes education, certified asthma educators (AEC) are recognized for their expertise in the content area of asthma pathophysiology and disease management (NAECB) and because of this they can recoup larger reimbursement sums for their efforts (NAECB). There are CPT reimbursement codes that are available only for the AEC to use (NAECB).

Implications for Research

This was a pilot study designed to test the feasibility of methods and assess the sample size for a larger trial and to suggest if relationships among variables were in the predicted directions. Even with small numbers, the hypotheses concerning improved asthma education was supported and there was trending in a positive direction for quality of life. These findings are promising and support the need for a larger study. This pilot also addresses
the power of a brief educational intervention to change health behavior and health outcomes. This study also has the potential to positively affect pediatric asthma outcomes by decreasing the associated morbidity and mortality related to lung remodeling, decreasing racial disparities in the prevalence and treatment of pediatric asthma and decreasing the financial burdens associated with asthma for the individual, family and society through changed behaviors.

This pilot sets the stage for testing of the variables in an appropriately powered RTC. The longitudinal design should be extended tracking subjects over a period of six months to a year. Given the fact that most of the subjects were exposed to tobacco smoke, raises the question of whether simultaneous parent education she be incorporated into the design. Offering basic asthma education with an emphasis on triggers and trigger avoidance and smoking cessation for the caregiver would be a positive alteration to the study design. When adult caregivers smoke, children are exposed to several health risks. Children are powerless to change the behavior of their caregiver and the fact also remains that they are also powerless to change their environment with respect to most environmental factors such as roaches, rodents, mold and mildew exposure and smoking exposure. Parents need to be included in the intervention programs so they can be educated regarding asthma signs and symptoms and trigger avoidance. Therefore while open airways is a good
program for asthma education, the program alone is not sufficient to improve pulmonary function.

Future research should also include determining the use of healthcare resource utilization for asthma symptoms to: include emergency department visits, unscheduled primary care visits and hospitalizations prior to and after the educational intervention and throughout the follow up period. In the pilot study, data regarding medication use was collected when the subjects were initially enrolled. Medication use, especially frequency of rescue medication use, is an important determinant of symptom control (NHLBI, 2007). In the future assessment of medication use should also be assessed before and after the intervention and throughout the follow up period to help determine the severity of asthma symptoms and symptom control.

Study Limitations

Significant changes in pulmonary function were not observed. Changes may have been seen over a longer period of time. Treatment dispersion was a problem in this study. While it would have been unethical for the PI not to address the symptoms that some in the control group were experiencing, the study protocol will need to be changed to allow the PI to be distanced from the control group so that they are not unintentionally exposed to the treatment.

Open Airways was intended to be used with children who were diagnosed with mild to moderate asthma. The curriculum was intended to be
delivered in a school setting. Use of this educational curriculum with children who had more severe disease may have altered the outcome. Also, while the curriculum is based on the developmental theory of Jean Piaget, it is intended to be used with children between the ages of 8 and 11 years of age. Subjects in this study were between the ages of 8 and 12, therefore they comprised two developmental groups: concrete operational and formal operational. This may also have affected the way the subjects perceived their disease, symptoms and concepts of quality of life, therefore it must be considered a limitation for this particular study.

Immediate Implications

Findings from this pilot have provided valuable data regarding the importance of providing asthma education. Given the perceived barriers of providers previously discussed, developing centers for asthma excellence may prove beneficial. A pediatric asthma center of excellence staffed with expert asthma educators would allow practitioners to care for children within a more holistic framework. Asthma education could be carried out over time with deliberate reinforcement of the concepts of asthma self care as recommended by the NHLBI asthma guidelines. The focus of care should include monitoring pulmonary function, symptom evaluation, asthma knowledge acquisition, health care resource utilization and quality of life. Considering the financial burden of asthma, children who are receiving disability for asthma and those who are applying for disability payments
should be seen at these types of centers. This has the potential to ensure they are receiving the proper education and management that will help bring their asthma under control, thus decreasing the need for disability resources.

The findings from this pilot study were shared with the business manager of Children’s Hospital of New Jersey at Newark Beth Israel Medical Center where most of the subjects had been recruited from the hospital’s inpatient and outpatient area. The manager queried medical records data to determine emergency department use and subsequent admissions for all pediatric patients admitted with asthma exacerbation or status asthmaticus from the time period of August 2009 thru February 2010. A review of the query data revealed that only one subject from the intervention group was admitted during that time frame while several of the subjects from the control group had emergency department visits for asthma exacerbation and one subject had multiple hospital admissions. With this information the administrator has asked that the pilot be continued as a service for Children's Hospital of New Jersey at Newark Beth Israel Medical Center. An extension request was approved by the institution’s IRB. Recruitment for the intervention has not yet started. Given the outcomes of this pilot, the PI has made changes to protocol and instrumentation. A request for amendment to the protocol is pending submission to the Newark Beth Israel Medical Center IRB. Once permission is obtained, randomization of subjects will begin. An
appropriate power analysis using a JAVA Scripts program, as described in chapter three, has determined that 63 subjects will be required in total.

The parents of high frequency users of the pediatric emergency department for asthma symptoms have been contacted and invited to participate in the study. As a result of the pilot study findings, the study proposal was modified to include a focus on parent education regarding asthma pathophysiology, triggers, especially tobacco exposure, and local resources for smoking cessation programs. In addition to the outcome measures reported in this study, the following have been added: symptom monitoring, resource utilization in terms of hospital admissions, emergency department visits and unscheduled primary care visits for acute asthma symptoms and monitoring of medication use, specifically short acting beta agonists and systemic steroid use.

The information gained from the process of conducting this pilot study and the outcomes of this pilot study are regarded as extremely valuable as the PI moves forward to establishing a career as a nurse scientist committed to the care of underserved and vulnerable children.
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Health Outcomes of Asthma Education

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Appendix A

COLUMBIA UNIVERSITY MEDICAL CENTER

Institutional Review Board

Protocol Number: #IRB-AAAB4137
Principal Investigator: Mary Byrne
Originating Department: SCHOOL OF NURSING - 586
IRB Approval Date: 02/22/2010
Expiration Date: 02/22/2011
Title: Impact of a Standardized Asthma Education Program for Children Ages 8-12 years old on Health Outcomes.
Dear Ms. Bowen:

The above mentioned protocol (2010.10) and consent form (version 3/12/10) were approved by the NBIMC Institutional Review Board on March 15, 2010. Research activities may now be initiated. The approvals were granted pursuant to the completion of changes requested by the IRB. All the stipulated changes to the consent form were made satisfactorily.

Please take note of the following:

Expiration date: **February 3, 2011.** A request for extension must be completed at least 30 days prior to the above expiration date.

Amendments
- Any changes in study procedures, subject population, recruitment or the consent process must be submitted for IRB approval prior to implementation.

Serious Adverse Events
- a. Any fatalities or life threatening adverse events related or possibly related to the research, occurring in an NBIMC subject must be reported to the IRB within 24 hours.
- b. Non-fatal or non-life threatening serious adverse events occurring in a NBIMC subject must be reported to the IRB within ten (10) working days.
- c. Non-NBIMC reports (ex. sponsor safety sheets) must be submitted to the IRB office within thirty (30) days of receipt.

Thank you for your cooperation.

Victor Parsonnet, MD
Chair, Institutional Review Board