# Statistical Analysis of Proposed Pediatric Asthma Screening Survey

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# Statistical Analysis of Proposed Pediatric Asthma Screening Survey

by

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DISSERTATION

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## ABSTRACT

*Background*: Poor asthma control is responsible for considerable morbidity and mortality among children (1). Current pharmacotherapy can suppress exacerbations of asthma symptoms. Thus, proper treatment of asthma is imperative in limiting the toll of this disease process on individuals as well as society. Treatment protocols tend to be based on measurement of asthma severity (3), but there are currently no widely accepted guidelines defining efficacy of treatment (i.e.- asthma control).

*Objective*: This study aimed to assess the construct validity and reliability of an asthma survey among a group of known asthmatics. Furthermore, we intended to determine the level of correlation between survey responses and asthma severity amongst survey participants as well as to discern the ability of the survey to discriminate between mild persistent, moderate persistent and severe persistent asthma.

*Methods*: Surveys from 207 parents/guardians of children aged 5-17 with physician-diagnosed asthma were evaluated for construct validity using Principal Components Factor Analysis. Reliability was assessed via Cronbach's alpha coefficient scale. Severity/response correlations were tested by Chi-square exact tests and the strength of each relationship was assessed using Spearman's correlation. Discriminating ability was analyzed by ROC curve, sensitivity, specificity and odds ratio.

*Results*: Construct validity testing showed that the scale is unidimensional with a Cronbach's alpha coefficient of 0.8076, indicating a high degree of reliability. Significant associations between asthma severity and each question were found, indicating that more severe asthmatics reported significantly greater symptom frequency (p-value range $<0.001$ - 0.019, Spearman's range = 0.152 - 0.396). ROC analysis yielded an area under the curve of 0.728. Analysis of the ROC curve indicated an optimal cutoff score of $\geq 6$ to indicate moderate-to-severe asthma. This cutoff yielded a sensitivity and specificity of 65.2% and 70.2%, respectively. Odds ratio was 4.407 (95% CI of 2.366 – 8.207).

*Conclusion*: Our results indicate that, among asthmatics, the survey is valid and reliable. We also noted more frequent symptoms as severity increased, indicating sub-optimal control among more severe asthmatics. Finally, the ability of the survey to predict asthma severity is not supported as the survey seems to assess asthma control, with higher scores indicating poorer control.

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## PRIOR PRESENTATIONS

- "Validity and Reliability Testing of an Asthma/Allergy Screening Questionnaire in a Dallas Inner City Pediatric Population." **J Alexander**, L Roy, N Ahmad, R Gruchalla
    - Presented at the American College of Asthma, Allergy and Immunology 2002 National Conference

- "Parent/Child Agreement Analysis of an Asthma/Allergy Screening Questionnaire in a Dallas Inner City Pediatric Population." **J Alexander**, L Roy, N Ahmad, R Gruchalla
    - Presented at 2003 UTSW Medical Student Research Forum

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# CHAPTER ONE
# Introduction

The increase in the prevalence of asthma over the past few decades has brought to light morbidity associated with this disease. Data obtained from the Asthma in America survey (1) note that among children surveyed, 11.6% had severe asthma, 16.8% had moderate asthma and 66.0% had mild asthma (5.6% were found to not have asthma). Also, almost one-tenth of asthmatics had been hospitalized overnight in the year preceding the survey and almost one-fourth had gone to an ER for asthma exacerbations in the same time frame. Almost half of the children with asthma surveyed had missed at least one day of school in the past year, and also about half of respondents stated that asthma limited their ability to take part in sports or recreational activities. In addition to the burden on patients as a result of their disease, there is also an economic cost to society. The estimated cost of asthma in the U.S. in 1990 was $6.2 billion, and approximately 50% of this cost is attributed to patients with severe asthma while only 20% of costs are attributed to patients with mild persistent asthma. (2) Thus, similar to many chronic diseases, the most highly affected subset of patients utilizes a disproportionate share of the available resources.

Fortunately, treatment protocols developed by the National Heart, Lung and Blood Institute's Practical Guide for the Diagnosis and Management of Asthma (3) outline a "stepwise" treatment plan based on asthma severity (see Tables 1 and 2). Under these guidelines, all patients with asthma should have a short-acting beta-2 agonist MDI available for acute asthma exacerbations, but further treatment with daily long-term control drugs, such as inhaled corticosteroids, depends on asthma severity. The initial

step, then, is to accurately assess severity according to the criteria listed in Table 1: daytime symptoms, nighttime symptoms and lung function tests. Note that this classification scheme is based on symptoms/spirometry obtained prior to treatment. Table 2 lists the recommended treatment for all patients over five years of age based on asthma severity. The NHLBI guidelines suggest beginning with the most intensive therapy indicated to gain rapid control and limit airway inflammation, and then a "stepping-up" or "stepping-down" in long-term control medications may be needed.

This study aims to test the validity and reliability of an asthma survey within a group of diagnosed asthmatics. In addition we sought to determine if there were differences in response patterns between mild persistent, moderate persistent and severe persistent asthmatics and, furthermore, determine the predictive value, if any, of the survey in discriminating between classes of asthma severity.

## TABLE 1: NHLBI Classification of Asthma Severity Guidelines

| | Days With Symptoms | Nights With Symptoms | PEF or FEV1 | PEF Variability |
|---|---|---|---|---|
| **Step 4 - Severe Persistent** | Continual | Frequent | <60% | >30% |
| **Step 3 - Moderate Persistent** | Daily | >5 per month | 60 - 80% | >30% |
| **Step 2 - Mild Persistent** | 3 - 6 per week | 3 - 4 per month | >80% | 20 - 30% |
| **Step 1 - Mild Intermittent** | <2 per week | <2 per month | >80% | <20% |

*Patients are stratified into asthma severity categories based on symptom levels and lung function tests prior to initiation of pharmalcologic therapy. Patients should be placed in the most severe category in which any feature they exhibit occurs.*

## TABLE 2: NHLBI Stepwise Asthma Management Guidelines (>5 years old)

| | | |
|---|---|---|
| **Step 4 - Severe Persistent** | Daily medications: | **High dose inhaled steroid** *AND*<br>Long-acting bronchodilator (**inhaled beta$_2$-agonist** or theophylline) *AND*<br>Steroid syrup or tablet (attempt to transition to inhaled steroids) |
| **Step 3 - Moderate Persistent** | Daily medications: | **Medium dose inhaled steroid** *OR*<br>**Low/Medium dose inhaled steroid** *AND* **long-acting inhaled beta$_2$-agonist**<br>*If needed*: Higher dose inhaled steroids AND long-acting bronchodilator |
| **Step 2 - Mild Persistent** | Daily medications: | **Low dose inhaled steroid**, **Cromolyn** or **Nedocromil** |
| **Step 1 - Mild Intermittent** | No daily medication needed. | |
| **All Patients** | **Short-acting inhaled beta$_2$-agonist** needed for symptomatic relief | |

*Treatment options for asthma patients are determined by assessment of asthma severity as outlined in Table 1. Preferred treatments are in* **bold** *type. It is recommended that treatment be reviewed every one to six months at which time medications can be increased to achieved control or titrated down to the lowest necessary dosage to maintain control.*

# CHAPTER TWO
# Description of the Study

## BACKGROUND

In the summer of 2002 a multi-center pilot project sought to validate an asthma screening survey developed by the American College of Asthma, Allergy and Immunology (ACAAI). Validity testing done on the data obtained at one institution, the University of Texas Southwestern Medical Center in Dallas, showed that the proposed survey was a poor instrument for diagnosing asthma (1). This conclusion was reached based on analysis that showed that the twenty questions in the ACAAI survey loaded into five separate components indicating that the survey measured five different variables (Table 3). Some of the smaller variables seemed to be measuring allergic or atopic variables (Components 2, 4 and 5, Table 3). Two other components (Components 1 and 3) seemed to be measuring asthmatic variables. The largest component, which also had the highest reliability coefficient, contained seven questions, which seemed to cluster around asthma symptoms (Component 1, Table 3)

The current project is a follow-up study which created a new survey using only the seven questions from Component 1 of the ACAAI survey. Internal validity and reliability testing was performed on a group of children known to have asthma with the expectation that the survey would identify a single component (i.e.- asthma) with high reliability. Furthermore, we determined the level of correlation between survey responses and asthma severity amongst survey participants as well as the ability of the survey to discriminate between mild persistent, moderate persistent and severe persistent asthma.

## Table 3: ACAAI Survey Construct Validity and Reliability

| | Total Sample N=182 Component | | | | |
|---|---|---|---|---|---|
| **Item** | **1** | **2** | **3** | **4** | **5** |
| Q1h: trouble breathing when running, playing, etc | .839 | | | | |
| Q1d: chest feels tight or hurts after activity | .805 | | | | |
| Q1g: wake up at night because of trouble breathing | .788 | | | | |
| Q1i: coughs when running, playing, etc | .723 | | | | |
| Q1b: hard time taking deep breaths | .709 | | | | |
| Q1a: make noisy/wheezy sounds when breathing | .519 | | | | |
| Q1k: problems with runny or stuffy nose | | .793 | | | |
| Q1f: wakes up at night coughing | | .791 | | | |
| Q1j: eyes get itchy, puffy or burn | | .738 | | | |
| Q1c: cough that won't go away | | .660 | | | |
| Q4: takes meds or uses inhaler for asthma | | | .821 | | |
| Q2: Dr/nurse said has asthma | | | .725 | | |
| Q1l: absent from school because of breathing problems | .574 | | .578 | | |
| Q3: stayed in hospital overnight because of breathing | | | .550 | .535 | |
| Q5: takes meds for allergies | | | .540 | | |
| Q1e: hard time breathing in cold weather | | | .538 | | |
| Q1n: trouble breathing around pets | | | | .854 | |
| Q1m: coughs when around pets | | | | .850 | |
| Q6: get very sick from bee or insect sting | | | | | .793 |
| Q7: some foods make child break out, swell | | | | | .520 |
| **Cronbach's Alpha Reliability Coefficient** | **.90** | **.84** | **.82** | **.87** | **.54** |

*Principal Components Factor Analysis of the 2002 ACAAI survey showed that the survey measured five underlying variables. The values shown represent which component each question had the strongest correlation with. Further, the Cronbach's Alpha Reliability Coefficient is shown for each component at the bottom of each column. The largest and most reliable component is Component 1, whose seven questions were utilized for the current study survey.*

## METHODS

Two hundred and seven patients with physician-diagnosed asthma from 5-17 years of age (mean = 9.44, 126 male, 81 female) were recruited from an outpatient pediatric pulmonary practice. The parents or guardians of the patients filled out the study survey based on their observation of their child over the past one month. The attending pulmonologist who was in the treating relationship with each patient determined each patient's asthma severity based on chart review of medications, spirometry and symptoms. Principal Components Factor Analysis was performed to test the construct validity of the scale, and reliability was assessed by Cronbach's alpha coefficient. Associations between levels of severity and responses to each of the questions were evaluated by Chi-square exact tests. The strength of each relationship was evaluated with Spearman's correlation. Survey scores were summated giving zero, one or two points for answering never, sometimes or a lot, respectively. This gives the index a possible range of zero to fourteen points. Finally, the discriminating ability of the summated score to predict asthma severity as mild persistent versus moderate-to-severe persistent using the summated score was evaluated by Recursive Operator Curve, sensitivity, specificity and odds ratio. There were insufficient numbers of severe persistent asthmatics to assess the ability of the survey to discriminate between all three asthma severity levels, thus the moderate persistent and severe persistent categories were combined for the analysis of the discriminating ability of the survey.

## RESULTS

A total of 207 children aged 5-17 completed the survey (126 male, 81 female). The frequency distribution of the scale approximates a normal distribution (Figure 1). The mean summated survey score was 5.11 with a median score of 5 and a standard deviation of 2.91. The 25$^{th}$ percentile score was 3 and the 75$^{th}$ percentile score was 7. Physician assessment of asthma severity was 68.1% mild persistent, 24.2% moderate persistent and 7.7% severe persistent asthmatics. There was no significant difference in asthma severity between sexes ($p = 0.525$).

Principal Components Factor Analysis was used to test the construct validity of the questionnaire. This analysis indicated that the seven items each loaded highly onto a single construct yielding a unidimensional scale. Factor loadings for each item ranged from .618 to .795, indicating a high degree of intercorrelation (Table 4). The Cronbach's alpha coefficient of 0.8076 indicates excellent reliability. These results demonstrate the construct validity and reliability of the scale in this sample of known asthmatics.

Significant associations between asthma severity and each question were found, indicating that more severe asthmatics reported significantly greater symptom frequency (See Figures 2-8; p-value range <0.001 - 0.019, Spearman's range = 0.152 - 0.396). The ROC analysis based upon a summated index score composed of all seven questions supports the predictive ability of the survey to discriminate between mild persistent and moderate-to-severe persistent asthma (Figure 9; AUC = 0.728). An evaluation of the sensitivity and specificity of the coordinates-point of the ROC curve indicated an optimal cut-off at six or greater (See Table 5), with values greater than or equal to six indicating

moderate-to-severe asthma. When utilizing a cutoff score of greater than or equal to six as an indicator of moderate-to-severe asthma, the data yield an odds ratio of 4.407 (95% CI: 2.366 – 8.207).

**Table 4: Current Study Survey Construct Validity and Reliability**

| | **Factor Loadings** |
|---|---|
| **Question 1**- Difficulty breathing during activity | 0.795 |
| **Question 2**- Chest tightness/pain after activity | 0.734 |
| **Question 3**- Difficulty breathing at night | 0.657 |
| **Question 4**- Cough with activity | 0.709 |
| **Question 5**- Difficulty taking a deep breath | 0.63 |
| **Question 6**- Noisy breathing or wheezing | 0.618 |
| **Question 7**- Missed school due to breathing problems | 0.621 |
| Cronbach's alpha = 0.8076<br><br>*Principal Components Factor Analysis for the current 2004 study survey showed that all seven questions loaded into a single component, indicating a single underlying variable, with each factor loading strongly onto the one component (range 0.618 – 0.795).. Cronbach's Alpha Reliability Coefficient revealed a high degree of reliability.* | |

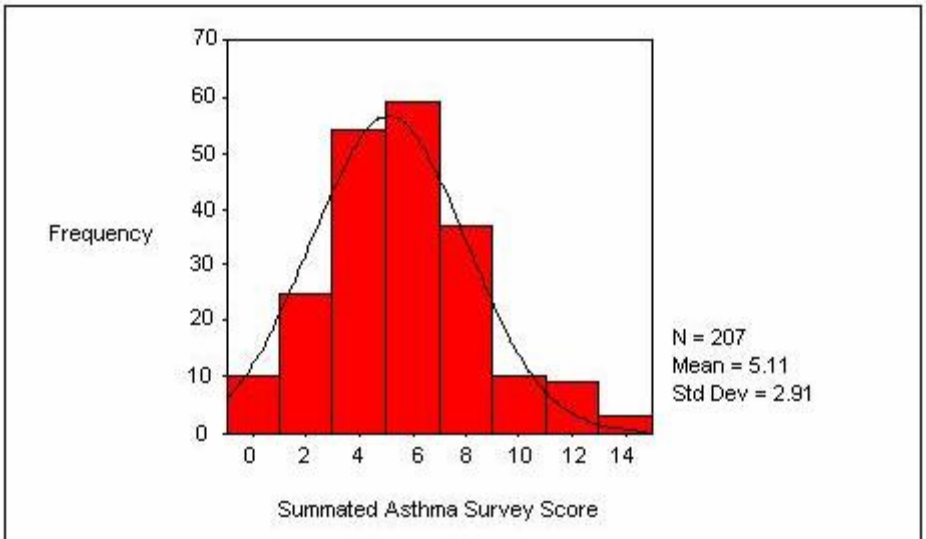
**Table 5: Current Study Survey Discriminating Ability**

| | Moderate-to-Severe Asthma | Mild Asthma |
|---|---|---|
| | N | N |
| Survey Score ≥6 | 43 | 42 |
| Survey Score ≤5 | 23 | 99 |

Chi-square = 23.2, $p < 0.001$
Odds Ratio = 4.407 (95% CI = 2.366 – 8.207), Sensitivity = 65.2%, Specificity = 70.2%

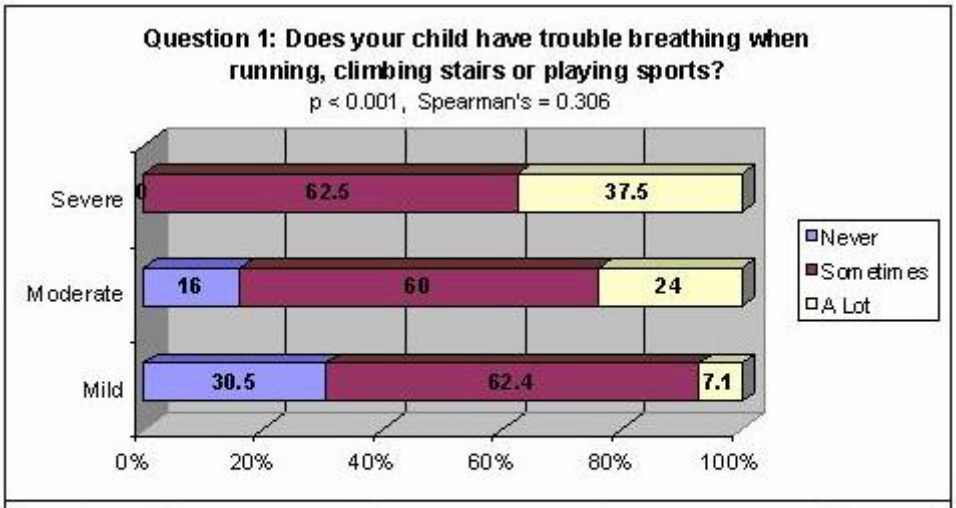
*When utilizing a cutoff score of greater than or equal to six to indicate moderate-to-severe persistent asthma, the data yield a sensitivity of 65.2%, specificity of 70.2% and Odds Ratio of 4.407 (95% CI = 2.366 – 8.207)*

**FIGURE 1: Distribution of Survey Scores**



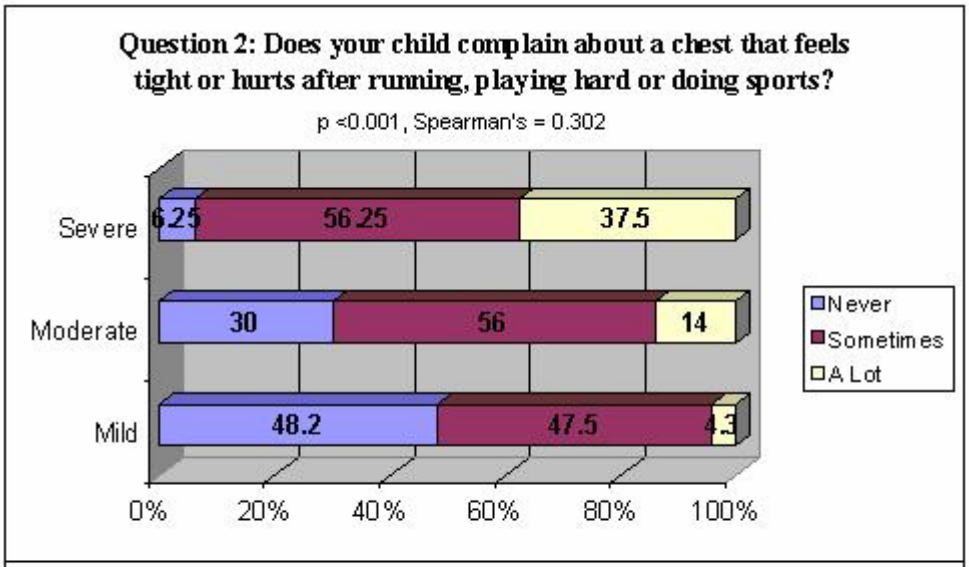

*The frequency distribution of the two-hundred and seven summated survey scores yielded a mean score of 5.11 with a 25th percentile of 3, a 75th percentile of 7 and a standard deviation of 2.91.*

**FIGURE 2: Responses to Question 1 Based on Asthma Severity**



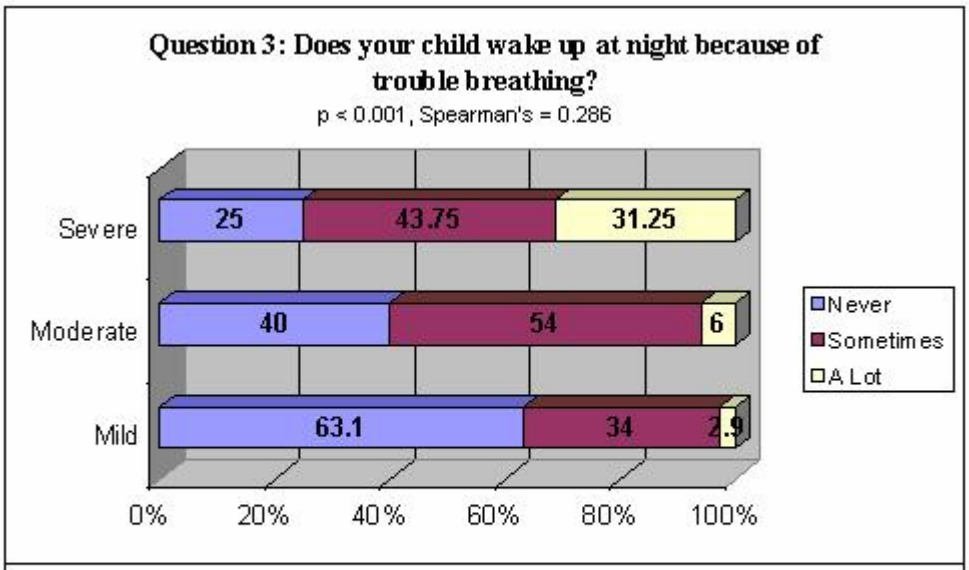

*Significant differences were found upon assessment of survey responses to Question 1 among each severity category (mild persistent, moderate persistent and severe persistent). Specifically, greater symptom frequency was reported as asthma severity increased.*

**FIGURE 3: Responses to Question 2 Based on Asthma Severity**



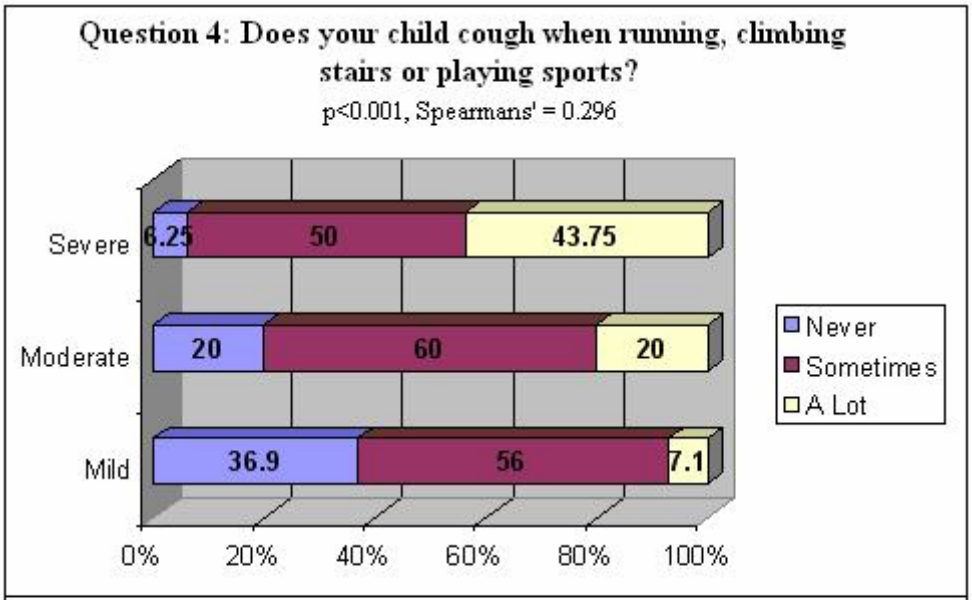

*Significant differences were found upon assessment of survey responses to Question 2 among each asthma severity category (mild persistent, moderate persistent and severe persistent). Specifically, greater symptom frequency was reported as severity increased.*

**FIGURE 4: Responses to Question 3 Based on Asthma Severity**



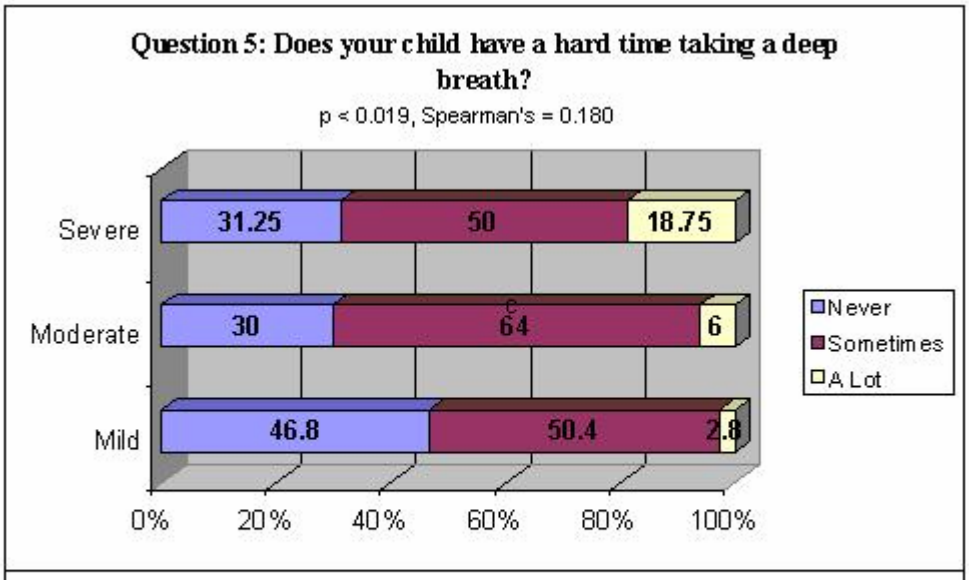

*Significant differences were found upon assessment of survey responses to Question 3 among each asthma severity category (mild persistent, moderate persistent and severe persistent). Specifically, greater symptom frequency was reported as severity increased.*

**FIGURE 5: Responses to Question 4 Based on Asthma Severity**



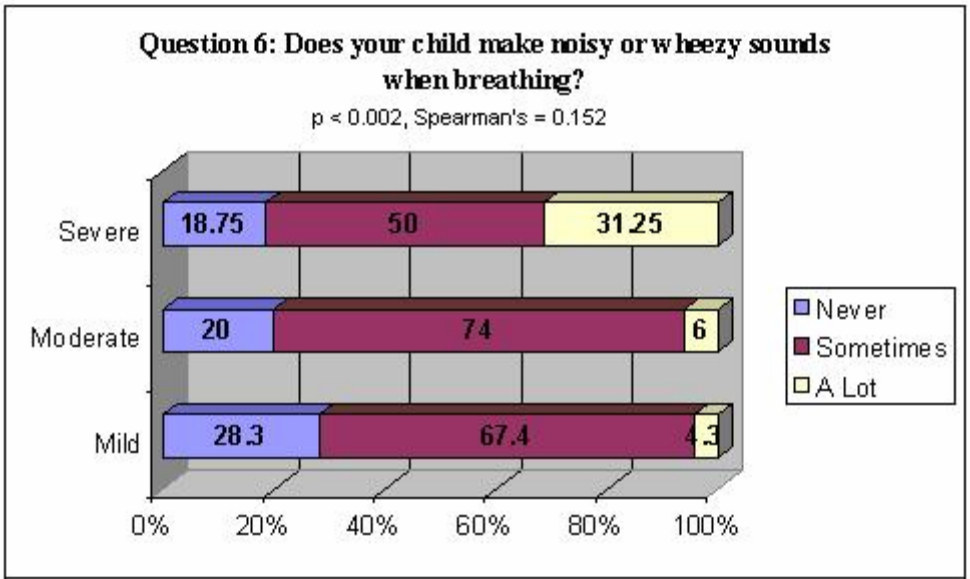

*Significant differences were found upon assessment of survey responses to Question 4 among each asthma severity category (mild persistent, moderate persistent and severe persistent). Specifically, greater symptom frequency was reported as severity increased.*

**FIGURE 6: Responses to Question 5 Based on Asthma Severity**



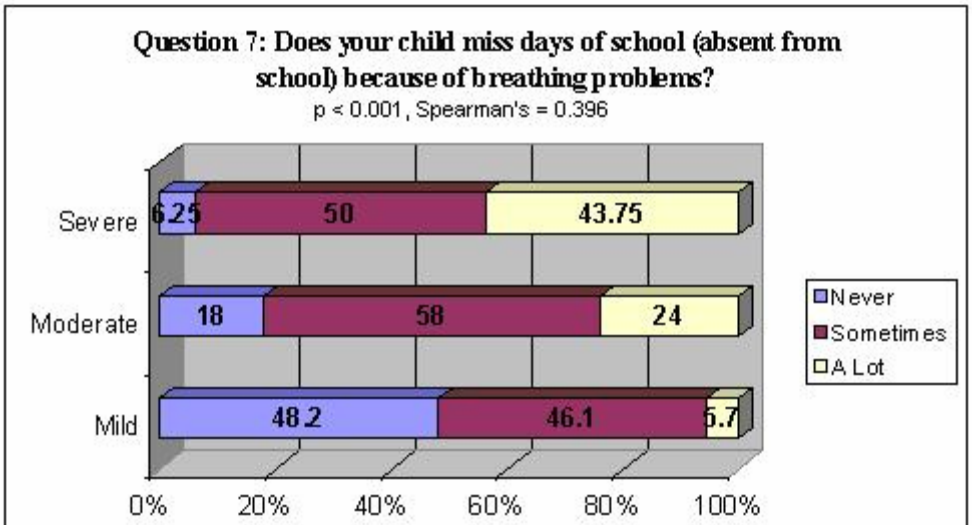

*Significant differences were found upon assessment of survey responses to Question 5 among each asthma severity category (mild persistent, moderate persistent and severe persistent). Specifically, greater symptom frequency was reported as severity increased.*

**FIGURE 7: Responses to Question 6 Based on Asthma Severity**



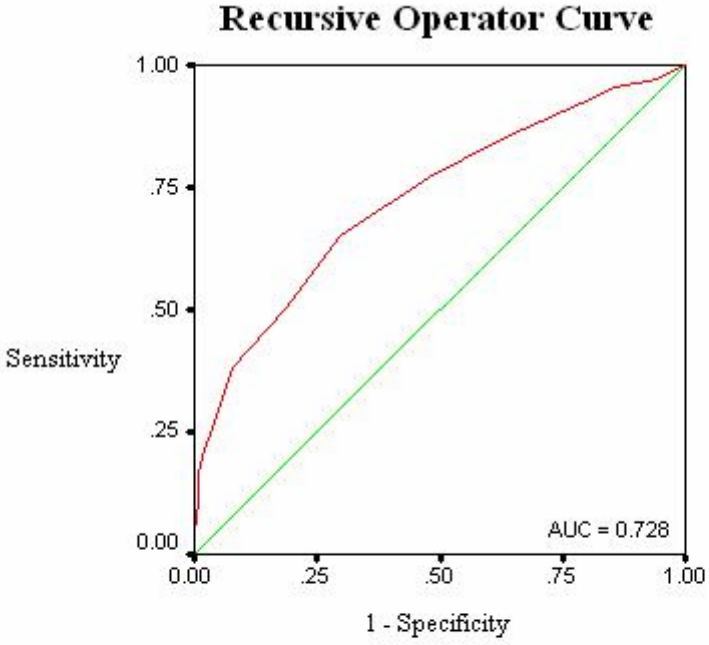

*Significant differences were found upon assessment of survey responses to Question 6 among each asthma severity category (mild persistent, moderate persistent and severe persistent). Specifically, greater symptom frequency was reported as severity increased.*

**FIGURE 8: Responses to Question 7 Based on Asthma Severity**




*Significant differences were found upon assessment of survey responses to Question 7 among each asthma severity category (mild persistent, moderate persistent and severe persistent). Specifically, greater symptom frequency was reported as severity increased.*

**Figure 9: ROC Curve**




*Recursive Operator Curve analysis of the summated survey scores shows an area under the curve of 0.728, thus supporting the predictive ability of the survey to discriminate between mild persistent and moderate to severe persistent asthma.*

## DISCUSSION

Results indicate that this survey is not only a valid and reliable indicator of asthma, but it also showed that more severe asthmatics are more frequently symptomatic (despite being under specialist care) and that there is indeed a correlation between higher survey scores and increasing asthma severity. An interpretation of our results requires an understanding of two intertwined concepts: asthma severity and asthma control.

Asthma has been classified according to severity in order to establish appropriate protocols for the treatment of asthma (Table 1 and 2). In contrast to severity, asthma control, as defined by Cockcroft, et al (5), is determined by the level of asthma symptoms and pattern of medication use. Good asthma control is defined as an increase in symptom free days, improved spirometry, decreased use of "rescue" medication, normal lifestyle, lack of nighttime symptoms and other morbidity. Essentially, asthma control is the absence of those symptoms that, prior to treatment, would indicate more severe asthma. Regardless of severity, when anti-inflammatory controller medications are properly used, patients generally become less symptomatic (i.e.- more controlled). Thus, asthma control is accomplished by the treatment of asthma via protocols based on asthma severity. A problem arises when severity guidelines are used to classify asthma patients already under treatment. If the pre-treatment (i.e.- severity) guidelines were utilized in treated asthmatics, then "well-controlled" asthma could be mistaken for "mild" asthma. In actuality, that "well-controlled" asthmatic may, without the benefit of therapy such as high-dose inhaled corticosteroids, qualify as a severe asthmatic.

With an understanding of the issue of asthma control versus asthma severity we can return to a discussion of the results of this study. In this study, the treating pulmonologist reported the asthma severity of each participant, as determined by chart review of medications, spirometry and current symptoms. Other studies have used similar criteria to stratify patients with asthma (6,7,8). We found more severe asthmatics to have more frequent symptoms when surveyed (Figures 2-8). These results are somewhat surprising since all patients were receiving specialty care. In light of this fact, one would expect that there would have been a uniformly low level of symptoms in patients of all severities. Our data show an inverse correlation between severity and control (i.e.- more severe asthmatics have poorer control which is manifested as more frequent symptoms).

Factors such as medications, compliance, inhaler technique, allergies and exposure to triggers (e.g.- tobacco smoke) were not evaluated. Further research would be warranted to determine if these factors contributed to the poorer control we saw in our more severe asthmatics. At the very least, these findings ought to serve as a warning to clinicians to be cognizant of factors that may contribute to poor control.

Another part of this study was to test the predictive ability of the survey in discriminating mild-persistent from moderate-to-severe persistent asthma. Specifically, using a cutoff score of $\geq 6$ yielded an odds ratio of 4.407 (95% CI: 2.366-8.207), thus giving the appearance that a score $\geq 6$ indicates an almost 4.5 times greater likelihood that such a child has moderate-to-severe persistent asthma. It is also possible, though, that the survey is not discriminating between asthma severity categories, but that it is showing that moderate-to-severe persistent asthmatics are almost 4.5 times as likely to have

increased symptoms. This conclusion seems more likely after taking into account the fact that we demonstrated a positive correlation between asthma severity and symptom frequency. Also, higher scores indicated more frequent symptoms which is, by definition, sub-optimal control, and more severe asthma correlated with more frequent symptoms, indicating poorer control as severity increased. When considered together, it seems that the survey was not predicting asthma severity in this population, but rather was discriminating between levels of asthma control.

One way to untangle the confusion between the concepts of asthma control versus asthma severity would be to use severity only in a pre-treatment capacity to guide initial therapy, as it was intended, and to develop a second stratification method for asthmatics receiving treatment that would assess control, thus assigning two measurements to each patient. For example, if one were categorized as a moderate persistant, well-controlled asthmatic, then it would give a much clearer picture of baseline symptoms/lung function (i.e.- severity) as well as the efficacy of current therapy (i.e.- control). This would effectively end the confusion about using severity criteria to describe the degree of control in patients already receiving treatment.

# CHAPTER THREE
# Conclusions and Recommendations

Conclusions:

The data show that the proposed asthma screening survey is a valid and reliable indicator of asthma. Our results also showed that symptoms were more frequent as asthma severity increased, thus we established an inverse correlation between asthma control and severity in this population (i.e.- poorer control or more difficulty in achieving control as severity increased). Furthermore, the discriminating ability of the survey in predicting mild persistent versus moderate-to-severe persistent asthma was not supported. The survey seems to be measuring degree of asthma control.

Recommendations:

The confusion over asthma control versus severity is due, in part, to the fact that there is no widely accepted language to describe how well asthma is being controlled in a treated patient. New studies should be initiated that attempt to develop stratification criteria for the degree of asthma control among populations of treated asthmatics. Also, further studies are warranted to assess what factors are responsible for the finding of poorer control among more severe asthmatics. These studies would require much more intensive scrutiny of patients and would need to evaluate each child's home and school environment for exposure to asthma triggers and allergens as well as assessment of compliance and inhaler technique. Also, our findings should serve as a reminder for clinicians to constantly assess the degree of asthma control among their more severe patients.

**APPENDIX: STUDY SURVEY**

***Please tell us how often your child has any of the following. Thank you.***

***Does your child**:*

| | Never | Sometimes | A lot |
|---|---|---|---|
| • Have trouble breathing when running, climbing stairs or playing sports? | ☐ | ☐ | ☐ |
| • Complain about a chest that feels tight or hurts after running, playing hard or doing sports? | ☐ | ☐ | ☐ |
| • Wake up at night because of trouble breathing? | ☐ | ☐ | ☐ |
| • Cough when running, climbing stairs or playing sports? | ☐ | ☐ | ☐ |
| • Have a hard time taking a deep breath? | ☐ | ☐ | ☐ |
| • Make noisy or wheezy sounds when breathing? | ☐ | ☐ | ☐ |
| • Miss days of school (absent from school) because of breathing problems? | ☐ | ☐ | ☐ |

**OFFICE USE ONLY:**
Study ID#: _____ Severity: _____ Age: _____ Gender: _____

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# Vitae

John C. Alexander was born on July 28, 1978 in San Antonio, Texas. After graduating from Winston Churchill High School in 1996, he went to Texas A&M University in College Station, Texas where he graduated Summa Cum Laude in 2000 with a Bachelor's of Science degree in Biomedical Science. Upon graduation from Texas A&M, he married his high school sweetheart, Tina, and began medical school at the University of Texas Southwestern Medical School in Dallas, Texas. Following his first year of medical school, John participated in a pilot project with Dr. Rebecca Gruchalla involving clinical research in pediatric asthma screening. After that summer, he presented an abstract for that initial project at the 2002 American College of Asthma, Allergy and Immunology National Conference, and another at the 2003 UT Southwestern Medical Student Research Forum. He continued doing research with Dr. Gruchalla throughout medical school and served as research coordinator for a follow-up study involving reevaluation of a subset of questions from the original pilot project. He is now a fourth-year medical student graduating in June, 2005 and will stay at UT Southwestern to begin his clinical training as an anesthesiologist in July, 2005.