CHARACTERIZATION OF ASTHMA IN ADULTS:
A COMPREHENSIVE INSTRUMENT

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In loving memory of my beloved grandmother,
Dora Scarpa

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CHARACTERIZATION OF ASTHMA IN ADULTS:
A COMPREHENSIVE INSTRUMENT

ABSTRACT

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This study sought to identify the attributes that represent the character of asthma and to identify how these attributes might be measured and modeled. The theoretical framework incorporated a research-developed framework identifying seven concepts: Physiological Intensity, Somatic Vulnerability, Self-Management, Medication Management Intensity, Symptom Intensity, Functional Status, and Well Being. These themes guided the development of the instrument, the Asthma Outcome Index.

An initial pool of 74 items was generated. Content validity was supported by four content experts. Readability, comprehension, and completeness were assessed by physician, staff, and patient focus groups. The 74-item Asthma Outcome Index was pilot tested with a purposive sample of 50 adults with asthma. The instrument was revised in light of ongoing content expert evaluation,

pilot participant feedback, and data analysis to yield a version with 85 items.

The 85-item instrument was tested on a purposive sample of 203 adults with asthma. Prior to analysis, items with item-to-scale correlations below 0.3 and at or above 0.7 were eliminated. Following this revisions, eight researcher-developed measurement scales were psychometrically tested for reliability and validity. Six of the eight scales, the "Symptom Intensity G Scale" (α = 0.757), The "Symptom Intensity B Scale" (α = 0.868), the " Management Intensity Scale" (α = 0.724), the "Functional Status Scale" (α = 0.765), the "Environmental-Impact Scale" (α = 0.744), and the "Somatic Vulnerability B Scale" (α = 0.785), were judged reliable using coefficient alpha and squared multiple correlation. Alpha correlation for the " Somatic Vulnerability A Scale" (α = 6312) and the "Medication Management Intensity Scale" (α = 0.673) was lower than the recommended by Nunnally (1978) for newly-developed scales. Validity of all measures was determined with confirmatory factor analysis using EQS 5.1 (Bentler & Wu, 1995) and found adequate under Bollen's (1989) definition of validity: all measurement variables were significantly linked to their hypothesized latent constructs. The latent constructs of the three factor

model were Severity, Self-Management, and Illness Intensity.

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CHAPTER I

INTRODUCTION

Asthma, a disease of reversible airway obstruction and airway hyperactivity, is a major health problem in the United States. According to a study conducted by the National Center for Health Statistics, asthma costs America more than $6 billion a year and accounts for nearly 1% of all United States health care costs (Weiss, 1992). While controversy exists regarding the source of this disturbing trend, increasing evidence suggests that preventive health care and education could decrease asthma morbidity and cost. Without a way to effectively measure the character of asthma, the outcome of treatment cannot be evaluated.

Asthma is difficult to characterize because of a complex interplay of biological determinants and environmental factors. Furthermore, asthma is characterized by episodes of severe symptoms separated by relatively symptom free periods. For these reasons, research instruments designed to evaluate health status, functional status and quality of life in other chronic

diseases are unable to approximate disease severity in asthma.

Problem of the Study

The desire to examine the character of asthma and the relationship that an outcome measurement might have in the field of asthma precipitated the focus of the present study. The problem to be addressed by this study was as follows: What are the attributes that represent the character of asthma and how might these attributes be measured and modeled?

Purpose of the Study

The purpose of this study was:

1. To develop, refine, and psychometrically estimate the properties of a researcher developed instrument, the Asthma Outcome Index (AOI).

2. To construct a hypothesized measurement model representing the character of asthma.

Rationale for the Study

A variety of measures are currently used to assess asthma; most are logical and seem reasonably effective but have not been adequately tested. Simple, brief measures are needed for greater specificity in describing variables and in assessing respiratory symptoms and other aspects of

asthma (Burney et al., 1987). Uniform assessment of disease severity is especially important as third-party payers increasingly require documentation of severity to determine eligibility for hospitalization and other forms of health care. In addition, research on outcomes is important, and such research requires the consideration of disease severity when analyzing the impact of any intervention. Since there is no agreed upon standard in the literature for assessing disease severity in asthma, creative approaches are necessary to more precisely define these important parameters.

Accurate assessment of asthma is central to assessing the health status and progression of disease, establishing standards for treatment, and determining requirements for individualized treatment plans. Identification of disease severity by patients and health care workers features prominently in mitigating morbidity and mortality. Therefore, a newly constructed instrument measuring the character of asthma has value in the area of health care.

Theoretical Framework

The theoretical framework for this study incorporates a researcher-developed conceptual model and synthesis of the related theories of measurement and generalizability, pathophysiology, well being, coping, social support,

self-care, functional status, and self-management. Measurement theory guides instrument development, and links theory and research. Generalizability theory extends measurement theory (Cronbach, Gleser, Nanda, & Rajartman, 1972; Waltz, Strickland, & Lenz, 1991) by providing a framework for assessing the measurement error and dependability of behavioral measurements.

Theoretical Model

The study was guided by the "Asthma Model." The model was developed by the researcher through the process of concept analysis, synthesis and derivation (Walker & Avant, 1988), as well as theory construction (Blalock, 1969). The development of the model included a preliminary step of reviewing the literature relevant to the character of asthma. A detailed examination of conceptual and methodological issues focused on existing instruments. Discussions related to the construct with physicians, nurses, respiratory therapists, social workers, and patient focus groups explored ideas and creative thought, as well as theory.

Physiology, psychology, sociology, and nursing comprised the primary area literature review. No comprehensive instruments measuring disease severity were identified. Open-ended questions were presented to asthma

patients and area experts in the field of asthma. From these endeavors, the concepts of the model were specified, and later theoretically described (see Figure 1). As noted in Figure 1, the identified latent constructs were physiological intensity, somatic vulnerability, self-management, medication management intensity, symptom intensity, functional status and well being. These constructs are considered critical attributes and consequences related to the character of asthma. Physiological intensity depicts the biological state and function of the immune and pulmonary systems. Somatic vulnerability represents the predisposition to illness affected by multiple psychosocial internal and external elements. Self-management is an ongoing activity and includes competence initiated or performed by an individual to achieve, maintain, or promote wellness.

Medication management intensity refers to the quantity of drug therapy used for the treatment of airway hyperactivity and airway obstruction. The duration and frequency of airway hyperactivity and the degree of airway obstruction is symptom intensity. Functional status is the impact of asthma on an individual's ability to perform age- appropriate activities under a broad range of circumstances. Well being describes the degree of

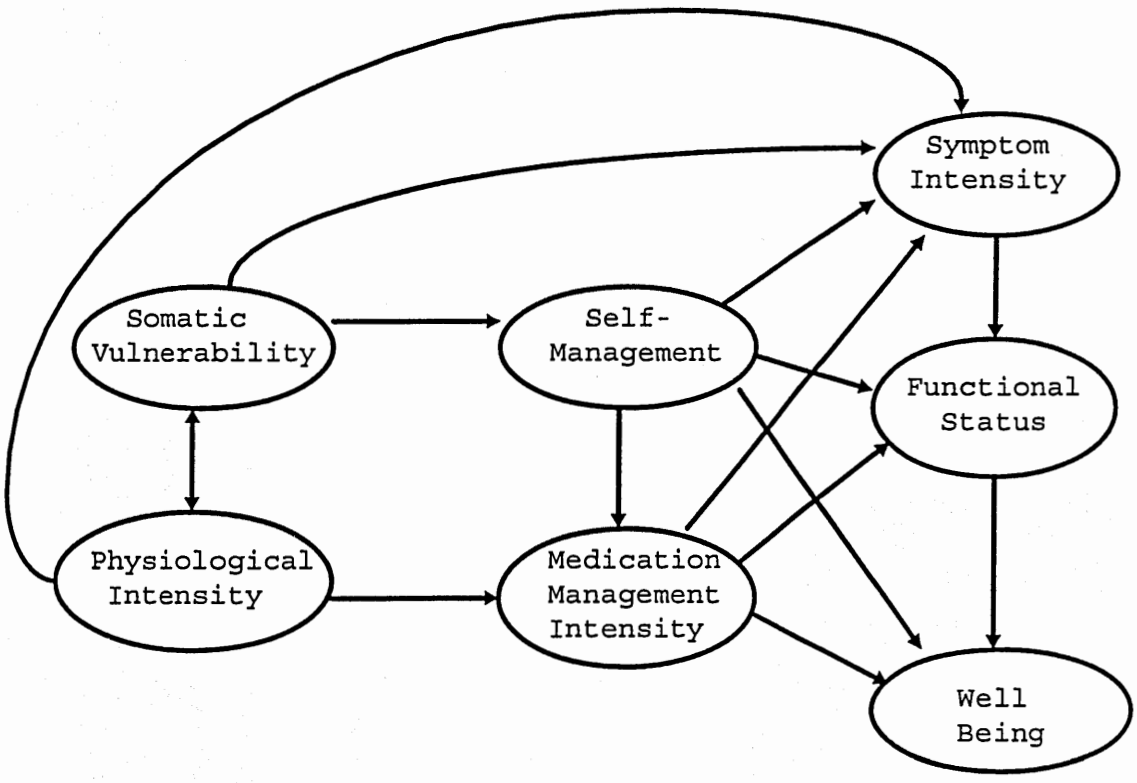

Figure 1. The Asthma Model.

emotional and social burden of asthma. These latent constructs are inherently unobservable but can be inferred by measuring a set of observable indicators.

Critical indicators of the constructs were outlined following the guidelines for conceptual mapping described by Waltz, Strickland, and Lenz (1991). Conceptual mapping is a strategy for expressing a framework of a study with diagrams of the interrelationships of the constructs and statements. Conceptual mapping leads to the selection of observable indicators for each construct guided by the theoretical definition. Empirical indicators for each latent construct are summarized in Table 1.

After the processes of concept analysis, synthesis and derivation (Walker & Avant, 1988) and conceptual mapping (Waltz et al., 1991) of observable indicators and dimensions for the variables identified as comprising the character of asthma, a model was constructed.

The goal of the present study was to develop, refine and psychometrically evaluate an instrument to measure the character of asthma. The concepts (variables) and the relationships identified in the model served as a framework for writing of items as well as evaluation of the instrument's validity. Nunnally (1978) asserts that instrument development postulates the relationships among

Table 1

Empirical Indicators for Each Latent Construct

Latent Construct	Empirical Indicator
Demographic characteristics	Age Sex Race Number of people living in home Number of children in the home Employment Income Education Insurance status Where prescriptions are filled Type of physician who cares for their asthma
Physiological intensity	Forced expiratory volume (FEV_1) History of bronchitis Onset of asthma Length of time since diagnosis Number of urgent care visits Number of hospitalizations Number of intubations History of hayfever, sinusitis, and esophageal gastric reflux Smoking history Aspirin allergy Other co-morbidities Number of medications taken
Somatic vulnerability	Coping Social support Locus of control
Self-management	Perception of adequate education and information Identification of sensitivities and exposures to allergens Use of management techniques
Medication management intensity	Identification, type, amount, and usage of asthma medication

Latent Construct	Empirical Indicator
Symptom intensity	Degree of wheezing, shortness of breath, cough, chest tightness, fatigue, irritability, and nervousness on good and bad days over 30 days Nocturnal awakening
Functional status	Degree of limitation in running, lifting, climbing, walking, and dressing
Well-being	Quality of life Number of well days during the last 30 days Perception of health status today and 1 year ago

the identified concepts (or attributes) thereby representing the theoretical model.

Measurement Theory

Classical test theory, upon which the reliability coefficient is based, assumes that an observed score is equal to the true score plus error. This assumption then leads to the formulation of the reliability coefficient as the ratio of the true variance to the error variance. For each person measured there is a true score and, in addition, multiple potential sources for error.

Measurement error is used in measurement theory to explain lack of complete predictability. Measurement error may be random or chance, and systematic. Random

error is caused by chance factors that confound the measurement. Random error affects the reliability or the consistency of measurements and, consequently, validity because reliability is a necessary prerequisite for validity. Systematic error arises from factors within the measuring tool, measurement process, or subject. Systematic error is the basis for the degree to which an indicator measures what it is supposed to measure by reflecting some other phenomenon (Waltz et al., 1991). Systematic error directly affects validity. Study design, sampling, method, instrumentation and statistical analysis provide limited means of controlling and reducing measurement error.

Methodological studies focus on instrument development. These studies seek to decrease random and systematic measurement error through estimates of reliability and validity (Burns & Grove, 1993; Nunnally, 1978). Reliability focuses on an instrument's consistent ability to measure a possessed attribute over time and among groups, and actually indicates the amount of random error in the instrument. Stability of an instrument focuses on assessing through correlation how reliable the instrument measures the response from one group initially and at some later time. Equivalence correlates comparable

or equal versions of an instrument. Homogeneity tests the internal consistency of an instrument's items by examining all possible correlations according to participants' responses. For reliability estimates, the higher the correlations, the more reliable the estimates of the instrument's ability to consistently measure a possessed attribute.

Validity addresses the extent to which the instrument truly indexes and reflects the abstract phenomenon being measured (Burns & Grove, 1993; Nunnally, 1978). Concerned with systematic error, validity estimates are possible regarding content, construct and criterion. Experts usually provide some content validity estimate of whether the instrument's items adequately sample the domain or content. Construct validity focuses on the degree to which the instrument's items accurately measure the phenomenon by comparing and contrasting responses to the items by groups and by other instruments. The instrument should reflect differences among those possessing opposite quantities of the attribute (contrasted groups) or another phenomenon (divergent), and correlations among those having similar quantities of the attribute (construct) or the same or like phenomenon being measured (discriminant, convergent). Another estimate of construct validity

involves assessing the relationship between the instrument's items and the phenomenon (factoring). Criterion validity involves predicting another measurement based on responses to the current instrument. Different types of validities exist, and when combined over time and testing accumulate estimates of how well the instrument actually measures the phenomenon (Waltz et al., 1991).

Thus measurement theory, using specific rules, directs the quantifications of a possessed attribute and provides guidelines for estimating how consistently and accurately an instrument measures the actually possessed attribute. Inherent in any measurement are random and systematic measurement error. With the goal to decrease error, estimates of reliability and validity provide direction toward increasing an instrument's consistent and accurate measurement of a phenomenon.

Generalizability Theory

Classical measurement theory partitions score variance into two components, true score variance and error variance. Generalizability theory acknowledges the multiple sources of measurement error by deriving estimates of each score separately. This approach provides a mechanism for optimizing estimates of

reliability (Shavelson, Webb, & Rowley, 1989; Waltz et al., 1991).

In generalizability theory two types of studies are done related to the assessment of measurement error, generalizability studies and decision studies. A generalizability study is concerned with estimating the magnitude of as many potential sources of measurement error as possible and is concerned with the extent to which a sample of measurements generalizes to a universe of measurements. A decision study is designed and conducted for the specific purpose of making a decision, such as describing examinees for placement or selection, comparing groups of subjects in an experiment or investigating the relationship between two or more variables (Crocker & Algina, 1986). In general, a generalizability study is conducted when a measurement procedure is being developed, while a decision study employs the measurement procedure for a specific purpose (Waltz et al., 1991).

One of the difficulties with traditional approaches to the estimation of reliability is that, although it is recognized that measurement errors may emanate from different sources, they are lumped together in the estimation process. Coefficient alpha gives the

reliability of a sum of indicators. However, in a structural equation model approach, the squared multiple correlation gives an estimate of the reliability of a single indicator (Bollen, 1989).

The nature of the decisions to be made with the data is also considered in generalizability theory. A distinction is made between relative decisions and absolute decisions. In relative decisions the focus is on the dependability of differences among individuals or the relative standing of individuals that result from the measurement procedure. Error components in relative decisions are due to variance associated with the rank ordering of individuals rather than the component that is the focus of the measurement. Absolute decisions are based on the observed score, which reflects the performance of an individual without regard to the performance of others. In this case, error is defined as all variance components associated with a score, except for the component of the object that is the measurement focus (Waltz et al., 1991).

Assumptions

Theoretical and research assumptions were identified for the study. Theoretical assumptions include:

1. The character of asthma is multidimensional.

2. Intrinsic biological severity in asthma is multidimensional.

3. Perceived and actual control of health status result not from a random event, but from interaction of events and forces that define, shape, size, and characterize the person (Janisch & Waddington, 1976).

Research assumptions identified for the study include:

1. The relationship examined in the hypothesized measurement model is causal (Bollen, 1989; Jöreskog & Sorbom, 1993; Lavee, 1988).

2. Physiological Intensity, Somatic Vulnerability, Self-Management, Medication Management Intensity, Symptom Intensity, Functional Status, and Well Being in adults with asthma can be measured.

3. Validity of a measure is the magnitude of the direct structural relation between the latent variable and its indicator (Bollen, 1989).

Hypotheses

The study was designed to develop and test the reliability and validity of the instrument, Asthma Outcome Index, by testing the fit between the measurement model and the sample data. The hypotheses for this study were:

Reliability

H1. The estimated degrees of homogeneity of items and scales for the Asthma Outcome Index (AOI) are greater than a Cronbach's alpha coefficient of .70 in persons with asthma.

Validity

H2. The theoretical measurement model for asthma demonstrates a statistical fit to the observed data.

Definition of Terms

Definitions of asthma and related concepts of physiological intensity, somatic vulnerability, self-management, medication management intensity, symptom intensity, functional status, and well being provide a theoretical description of the phenomenon. Theoretical definitions of disease severity with its model elements reflect abstract, ideal conceptualizations. Operational definitions offer a method of measuring the theoretical phenomena in the real world.

Disease Severity

Theoretical definition. Disease severity is the baseline function of current disease status and the intrinsic manifestation of disease lability. It is the dimension of asthma that is an integrating or unifying

factor manifested through physiological intensity, somatic vulnerability, self-management, medication management intensity, symptom intensity, functional status, and well being.

Operational definition. The character of asthma is measured by a person's response to items on the subscales collectively known as the Asthma Outcome Index (AOI).

Physiological Intensity

Theoretical definition. Physiological intensity is a biological state and function of the immune and pulmonary systems.

Operational definition. Physiological intensity is measured by a person's response to items on the AOI instrument section and health care provider input designated by the researcher.

Somatic Vulnerability

Theoretical definition. Somatic vulnerability is the predisposition to illness affected by multiple internal and external elements, for example, locus of control, coping, and social support.

Operational definition. Somatic vulnerability is measured by a person's response to items on the AOI instrument section designated somatic vulnerability by the researcher.

Self-Management

Theoretical definition. Self-management is an ongoing activity and competence initiated and performed by an individual to achieve and maintain control over their asthma.

Operational definition. Self-management is measured by a person's response to items on the AOI instrument section designated self-management by the researcher.

Medication Management Intensity

Theoretical definition. Management intensity is the quantity of drug therapy needed for the treatment of airway hyperactivity and airway obstruction.

Operational definition. Management intensity is measured by a person's response to items on the AOI instrument section designated medication management intensity by the researcher. It is a person's response to what medication they are taking for their asthma and not necessarily reflective of what has been prescribed.

Symptom Intensity

Theoretical definition. Symptom intensity is the duration and frequency of airway hyperactivity and the degree of airway obstruction. It is subjective in nature.

Operational definition. Symptom intensity is measured by a person's response to items on the AOI

instrument section designated symptom intensity by the researcher.

Functional Status

Theoretical definition. Functional Status is the impact of asthma on an individual's ability to perform age-appropriate activities under a broad range of circumstances.

Operational definition. Functional status is measured by a person's response to items on the AOI instrument section designated functional status by the researcher.

Well Being

Theoretical definition. Well being is the degree of emotional and social burden of asthma.

Operational definition. Well being is measured by a person's response to items on the AOI instrument section designated well being by the researcher.

Limitations

The following limitations were identified as potentially affecting the conclusions of this study:

1. Volunteer participants may respond differently to the instrument than the target population.

2. Response set bias, either responding in a socially desirable manner or responding negatively, may alter study results.

3. The instrument's items may increase anxiety or awareness, which may influence participant's response to items.

4. The researcher may unknowingly affect the participants' volunteerism and/or response to the instrument.

5. The study employs a purposive sampling technique, and, therefore, random selection is not possible.

Delimitations

The following study delimitations were identified:

1. Participants were located in the southwestern United States, aged 18-60.

2. Participants were limited to those able to read and write English.

3. Participants were consciously and voluntarily chosen to participate in the study.

Summary

Chapter I introduced the character of asthma as an important construct to study in nursing. A theoretical framework presenting seven latent variables was outlined.

Further, a conceptual map of the seven variables developed by the researcher was displayed. Additionally, the need for a valid and reliable measure of severity consistent with the theoretical framework was indicated. The development and psychometric assessment of an instrument for asthma was presented as the purpose of the study. Finally, the assumptions, hypotheses, limitations, and delimitations of the study were enumerated.

CHAPTER II

REVIEW OF THE LITERATURE

Asthma Severity

Aas (1981), in reviewing the heterogeneity of asthma, defined five grades of severity based on symptoms, functional restriction, and type of therapy needed for management. Bailey (1994) concluded that asthma severity is multidimensional, including at least three components: symptom intensity, airflow impairment, and management intensity. Gonnella, Hornback, and Lewis (1984) defined severity across different health conditions to be the "likelihood of death or residual impairment as the result of a disease, without consideration of treatment" (p. 637).

One of the most fully developed models characterizing the multidimensional configuration of disease severity was developed by Stein (1987) (see Figure 2). In conceiving this model, Stein recognized that severity is not just a measure of intrinsic biological severity, but rather a complex concept encompassing how an individual is affected by an illness; how that illness affects the individual's

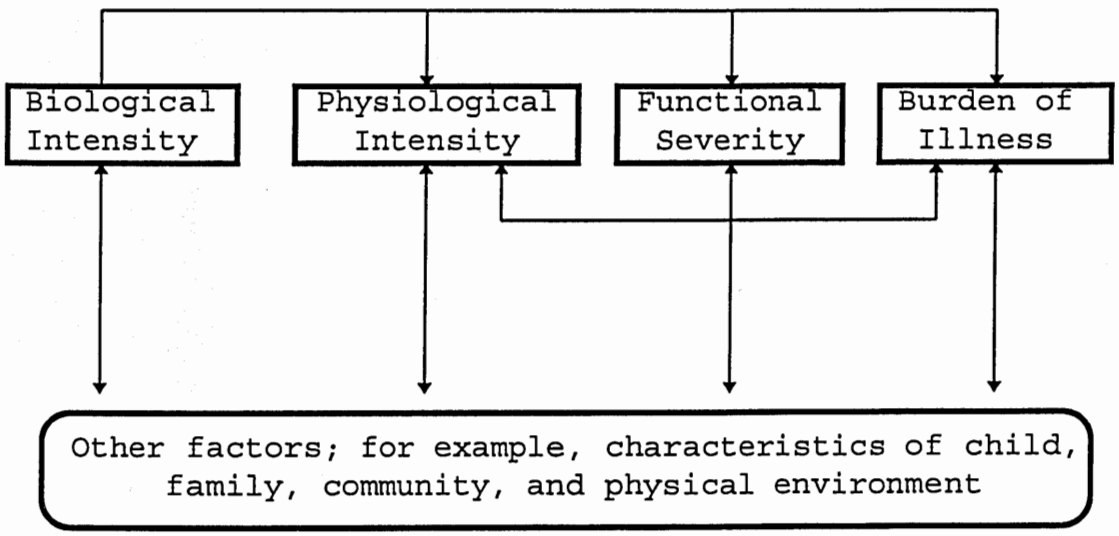

Figure 2. Multidimensional configuration of disease severity.

Note. Stein, R. E. K., "Severity of illness: Concepts and measurements," by R. E. K. Stein, 1987, Lancet, 2, p. 1507. Reprinted from Severe Asthma: Pathogenesis and Clinical Management, p. 3 by courtesy of Marcel Dekker, Inc.

ability to function in his or her environment, and how it affects the individual's family and society in general.

Busse et al. (1994) stated that the desirable features of treatment-based severity scales should include the following:

1. The scale should be based on a standard approach of asthma treatment, such as advocated by the guidelines of the National Asthma Expert Panel (1995).

2. The scale should be relatively simple to use and be applicable in both the clinical and research environment.

3. The scale should reflect severity of disease even if additional or more intense treatment of disease has resulted in reduction of symptoms.

4. The scale should take into account previous observations that patients with disease of apparently equivalent severity may be treated more aggressively by specialists than by primary care physicians.

5. The framework of a treatment based severity scale should be flexible to permit adaptation of the scale to include newly available medications or changes in recommended treatment strategy.

The following review of the literature explains the researcher-developed model characterizing asthma in adults.

Physiological Intensity and Existing Instruments

In considering the character of the physiological intensity in asthma, the most precise instruments are those that reflect the biological impact of the disease on the target organs. The biological impact of asthma is assessed by determining lung function, therefore pulmonary function testing is a key measure. In the future physiological intensity may include the degree of inflammation in the lung as well. These types of physiological measures would include assays for eosinophil cationic protein (ECP), cytokines, and tryptase. Also, patterns of T-cell activation may provide a useful physiological measure of immunological severity, providing new methods for grading asthma severity in studies (Bentley, 1992; Walker, 1991).

Pulmonary function testing has for years been the principal physiological measure of end organ severity. This has been predicated on the assumption that variable airway obstruction is the principal pathophysiological

pathway process in causing symptoms of asthma (Bentley, 1992).

The FEV_1 has been the most common measure of function and is considered the most reliable measure of airway obstruction and change in pulmonary function (Enright, 1994). The percentage of predicted FEV_1 is the basis for many grading systems of asthma severity (Table 2). Typical spirometric abnormalities during an acute attack include reductions of the forced expiratory volume over 1 second (FEV_1), peak expiratory flow rate, and FEV_1/forced viral capacity (FVC) ratio and an increase in the FEV_1, greater than 15% in response to a bronchodilator.

Abnormalities also include a decreased vital capacity and an increase in functional residual capacity, total lung capacity, and residual volume. Pulmonary function testing can be used to characterize asthma severity in two ways: (a) airway function, and (b) bronchial hyperreactivity. Pulmonary function abnormalities are similar regardless of the triggering mechanism of the disease.

Despite the abundant literature on the use of lung function as an epidemiological measure of asthma severity, there is a paucity of population-based studies of lung function that characterize the proportion of persons with

Table 2

Comparison of FEV_1 Criteria for Assessing Asthma Severity

Authors	Severity Criteria
Tai and Read	FEV_1 < 1.0 L often associated with PaO_2 </=60
Rees et al.	FEV_1 < 0.7-0.7 L often associated with PcO_2 </=60
McFadden et al.	FEV_1 < 25% of predicted — Severe FEV_1 > 26-50% predicted — Moderate FEV_1 > 51% of predicted — Severe
Franklin	FEV_1 near normal — Mild to absent FEV_1 = 0.3-0.8 L — Moderate Marked hypoxia — Severe
Kelsden et al.	FEV_1 improved after treatment < 400 mL-67% relapse FEV_1 improved after treatment > 400 mL-29% relapse
Snider	Stage 1: FEV_1 (L) 2.0; P_{co2} —; Grade Mild Stage 2: FEV_1 (L) 1.0-2.0; P_{co2} < 35; Grade Moderate Stage 3A: FEV_1 (L) 0.75-1.0; P_{co2} 35-45; Grade Severe Stage 3B: FEV_1 (L) 0.75; P_{co2} > 45 Stage 3C: FEV_1 (L) Severely impaired; P_{co2} —
Norwak et al.	FEV_1 </=0.6 L initially and </=1.6 L after treatment required admission or relapsed
Enright	FEV_1 (% predicted) — Severity 70-100 — Mild 60-69 — Moderate 50-59 — Moderately severe 35-49 — Severe < 35 — Very severe
Bolliger	FEV_1 <25% of predicted and PEF <30% of predicted

Note. Corre, J."Assessing severity of adult asthma and need for hospitalization." Reprinted from Annals of Emergency Medicine, 14, p. 48 by courtesy of Marcel Dekker, Inc.

severe disease. In one of the few population-based studies of persons with asthma, Kelly (1988) studied 286 subjects

as part of a longitudinal study of childhood asthmatics. At follow-up (done at age 28), 28% of the subjects fell into the most severe subgroup. In this study, severe was defined as wheezing more than once per week in the past 3 months. The FEV_1 (+/- standard deviation) of this group with severe disease was 87.3 +/- 18.7% of predicted. Remarkably, only 31% of the patients assigned to this group on the basis of symptoms had any abnormalities in their FEV_1 (Enright et al., 1994).

Peak expiratory flow rate (PEFR) is also a useful method to assist in measuring changes in airway function since it correlates well with FEV_1 and is therefore indicative of the presence or absence of airway obstruction. The availability of peak flow meters made this measurement invaluable in the outpatient treatment of asthma. Bollinger (1992) defines acute severe asthma as a PEFR of less than 30% predicted and a FEV_1 of less than 25% predicted. Most population studies, however, do not include many patients with this degree of obstruction (Kelly, 1988; Sherman, 1992).

No consensus has been found to date on the relationship of plasma eosinophilia to the severity. The correlation of eosinophil count with asthmatic predisposition was supported by Burrows et al. (1991).

Among subjects below age 55, ventilatory function was significantly low and symptom rates were significantly increased only when there was allergy skin-test reactivity in addition to eosinophilia. This study, however, did not link the degree of eosinophilia with the severity of asthma.

Multiple studies have shown a correlation between serum IgE levels, skin testing, and asthma (Burrows, 1989; Gergen & Turkletaub, 1991). Burrows (1991) linked skin test reactivity to impaired pulmonary function. However, no studies linked the degree of skin test reactivity or the level of serum IgE to asthma severity. A more recent study by Shakib (1994) found no relationship between the level of elevation of IgE antibodies and the severity of asthma. Thus, though serum IgE levels may be useful in studying risk factors for allergic sensitization leading to asthma, they have no current role in the assessment of asthma severity (O'Connor & Weiss, 1994). In conclusion, there have been a number of studies demonstrating physiological intensity, yet the role of any of the current measures of physiological intensity characterizing disease severity is less clear.

Somatic Vulnerability and Existing Instruments

Support for the association of somatic vulnerability with asthma severity can be traced to Maimonides in 1190.

> When in mental anguish, fear, mourning or distress . . . his agitation affects his respiratory organs and he cannot exercise them at will. . . . The cure of such conditions . . . lies not in food recipes, neither in drugs alone, nor in regular medical advice . . . psychological methods are a greater help.

Psychosocial issues do become important determinants of course and outcome in asthma. Since Maimonides' time, the literature is replete with anecdotal reports, and scientific studies linking psychosocial factors to asthma severity.

While evidence mounts that somatic vulnerability measures have roles in the etiology of asthma, it is unclear whether this vulnerability is secondary to one primary abnormality or whether there are multiple independent somatic vulnerabilities (Creer et al., 1992). How the concept of psychosocial predisposition interacts with subsequent exposures to emotional, familial, and medical influences to determine the severity of airway disease and the disability secondary to asthma is also unclear. Variables that might occur between the initial somatic predisposition and the severity of asthma symptomatology include environmental stresses, viral

illness, learned responses, stress, temperament, family coping mechanisms, behavior, and medications. The most compelling data have been derived from clinical and epidemiological studies, particularly in children. These studies show the effects of social environmental factors (maternal smoking, poverty, and crowding) interfacing with behavioral factors. This interface notes four types of observations linking emotional factors, neuroimmunology, temperament, and neuropsychiatric side effects associated with asthma medications (Creer et al., 1992).

Beginning two decades ago, several studies have been directed at understanding the contributions of emotional factors, such as suggestion, to asthma. The work of McFadden (1969) exemplifies this research. In this study, 29 adults with asthma were told they were going to inhale increasing concentrations of an aerosolized allergen to which they were allergic. In fact, a saline aerosol was inhaled. Fifteen of the 29 subjects developed a significant increase in their airway resistance: 14 subjects did not. When rechallenged in a later session, 13 of the 15 original reactors continued to show significant increases in airway resistance. A number of studies have been conducted to investigate the role of

suggestion and asthma. These investigations verify a strong emotional factor in a subgroup of asthmatics.

An important area in neuroimmunological research concerns the effects of neuropeptides mediated at peripheral sites of nerve endings. It is believed that the high content of neuropeptides in neurofibers may affect vascular permeability and smooth muscle contractility. These effects may be, in part, mediated centrally. Current research is directed at developing the technology to prove or disprove some of the hypotheses that have been generated from both animal and in vitro studies (Creer et al., 1992).

The relationship of temperament, including personality and behavioral factors, has been studied in childhood asthma. Rossier (1994) explored the physiological correlates of two behavioral patterns by focusing on toddlers who are inhibited or uninhibited in unfamiliar situations. In a prospective study, noting these behavioral characteristics at 21 months old, they reported significant consistency in these particular behavioral characteristics through 7 years of age, as well as associated differences in cortisol levels and heart rates between groups. Rossier also described significant differences in the prevalence of allergies and, in

particular, asthma, with the inhibited group showing a higher prevalence of the disorder.

The importance of emotional stress in precipitating asthma attacks ranges from the minimal to major. Precipitation of attacks may occur where personality styles interfere significantly in compliance, or where there is a major depressive element. In comparison to non-asthmatics, asthmatics can display greater facial emotion expression, more expression of hostility, more aggressive responses to sentence completion and higher scores on panic-fear scales (Creer et al., 1992).

Kinsman and associates (1982) have shown that asthmatics who were either low or high on the dimension of panic fear on the Minnesota Multiphasic Personality Inventory (MMPI) had more hospitalizations for asthma than those who scored in the moderate range (Dirks, 1981). They hypothesized that too little anxiety was associated with denial of symptoms and delay in seeking treatment. High levels of anxiety were associated with poor discernment of respiratory versus anxiety symptoms, leading to over-utilization of medical treatment. Stein (1987) reported an association between the inability to detect respiratory sensations and a defensive style of

repression, which is characterized by reports of low anxiety despite being involved in stressful situations.

The empirical basis for somatic vulnerability is a comprehensive integration of multiple cognitive and behavioral theories. Within this concept a person is viewed as having a differential response patterns associated with reactions which are necessary to achieve active coping (vulnerability) when faced with asthma. The link between somatic vulnerability and severity arise from multiple levels of biopsychosocial influence. Work in this area has been limited thus far by small sample sizes and imprecise measurements.

Self-Management and Existing Instruments

In considering the nature of asthma self-management, it is important to note that the focus is on behavior, knowledge, attitudes, and beliefs. It is also important to clarify whose behavior is being considered. At times, patient self-management and family management have been treated as though they were the same thing. To date, researchers have examined the situation in which children and parents on behalf of a child, assume responsibility for the management of asthma. This joint management has been referred to as family management. Although family

issues have been a subject in studies of adults, there are no studies considering the behaviors of family members in addition to that of the adult patient.

The theoretical construct, self-regulation postulates that individuals are predisposed to take action to handle problems by virtue of internal knowledge, attitudes and beliefs, external models of behavior, technical advice, service, and money. Processes of self-regulation include the ability to observe and make judgments, react to one's own behavior, and teach individuals management strategies, prevention, symptom management, negotiation, and communication. If these management strategies are effective, expected outcomes are the patient's personal goal will be reached; physiologic and psychological health status will be improved; and health care use will be appropriate. A range of good studies of adult patient behavior are available and provide some evidence that these three outcomes can be attained.

The instruments used in these studies were as follows:

1. Living with Asthma Questionnaire (Hyland et al., 1991).
2. Asthma Opinion Survey (Richards et al., 1989).
3. Asthma Attitude Survey (Snyder et al., 1987).

4. Asthma Attitude Test (Tehan et al., 1989).

5. Asthma Self Efficacy Scale (Tobin et al., 1987).

6. Multidimensional health Locus of Control (Wallston, 1978).

7. Feelings and Attitudes (Wilson et al., 1992).

8. Knowledge, Attitude and Self-Efficacy Questionnaire (Winder et al., 1992).

9. Baseline Assessment (Bailey et al., 1990).

10. Revised Asthma Problem Behavior Checklist (Snyder et al., 1987).

11. Asthma Diary (Snyder et al., 1987).

12. Enrollment Questionnaire (Wilson et al., 1992).

13. Two Weeks Diary (Wilson et al., 1992).

14. House Dust Mite Asthma Self Rating Scale (Huss, 1992).

15. Observation Checklist of Environmental Control Measures (Huss, 1992).

16. Enrollment Questionnaire (Wilson et al., 1992).

17. Asthma Knowledge Test (Bailey et al., 1990).

18. Asthma Information Quiz (Snyder et al., 1987).

19. Asthma Information Test (Wilson et al., 1992).

In existing asthma management research literature, little attention has been paid to the validity and reliability of instruments. Most appear to have face

validity, but other aspects of validity have not been explored. Only two researchers reported the internal consistency of their instrument or their inter-rater reliability scores. There is, however, a solid foundation for the development of more sophisticated and refined self-management assessment measures in the future.

Clark and Starr-Schneidkraut (1994) identify several factors in assessing levels of management by patients. They are as follows:

1. Measures should be behavioral.

2. Measures should include the prevention and attack management strategies postulated by clinicians, for example the Expert Panel Report on the Guidelines for Diagnosis and Treatment of Asthma.

3. Strategies needed for communication and negotiation within the family, community, and health care system should constitute part of asthma management measures.

4. Measures should be reliable and valid.

5. Direct observation should be used to verify self-reported behavior or as an independent measure of management.

6. Behavioral data assessing patient management should be considered in their relationship to desired

endpoints, quality of life, physiologic status, level of symptoms, functional status, side effects, and health care utilization. They should also be considered as they correlate with intrapersonal factors, knowledge levels, attitudes, feelings and beliefs about asthma and external resources. These predisposing factors may be important to consider in asthma management education programs and constitute avenues for understanding and changing behavior (Lahdensuo et al., 1996).

The management of the adult with asthma plays an integral role in symptom severity. Symptom severity is influenced by patient education, avoidance of triggers, and titrated inhaled bronchodilators and maintenance of inhaled anti-inflammatory agents.

Medication Management Intensity and Existing Instruments

Over the past decade, there has been a dramatic change in the pharmacological approach to asthma treatment. This change is based on the division of available agents into those that act symptomatically, reversing the cause of airflow obstruction but that do not treat the underlying inflammation, and those that act preventatively, reducing the underlying inflammatory process and eventually affecting airflow obstruction.

Depending on the severity of the patient's asthma, symptomatic treatment is initiated to control the patient's airflow obstruction while specific treatments often require time to act. In other words, all patients who have more than occasional symptoms are treated with bronchodilators and antiinflammatories, along with a limited course of symptomatic drugs as well. The plan is to reduce the symptomatic agents as soon as the patient responds to these approaches.

Adrenergic Agonists

Development of effective, airway selective, inhaled beta-adrenergic agonists has led to their preferential use as symptomatic treatment of asthmatics in all stages of severity. As such, inhaled beta-agonists are the mainstay of symptomatic therapy. The major side-effects of these agents are tremor, palpitations, and metabolic disturbances. Arrhythmias have been reported, particularly after administration of terbutaline and albuterol, especially in patients with preexisting heart disease. Prospective studies suggest that chronic use of beta-agonists can paradoxically increase the airway responsiveness in some asthmatics. While these issues require consideration, beta-agonists are still the first

line symptomatic drug of choice (Kaliner & Lemanske, 1992).

Methyxanthines

Theophylline is currently the most widely used drug in the methyxanthine class. Although controversial, the major pharmacological activity of the methyxanthines is likely to involve relaxation of bronchial smooth muscle, an effect that is the greatest when the muscles are constricted. Theophylline also improves contractility of the diaphragm, rendering it less susceptible to fatigue, reverse mucosal edema, inhibits mast cell degranulation and accelerates mucocilliary transport (Holgate & Church, 1989; Kalliner & Lemanske, 1992).

Until recently, theophylline was considered the first drug to use in chronic asthma, however the current trend is to use theophylline as symptomatic treatment only after first using inhaled beta-adrenergic agonists. The side-effects of theophylline include nervousness, nausea, vomiting, anorexia, personality changes, hyperactivity, abdominal discomfort, headache and seizures.

Anticholinergics

Inhaled anticholinergics may be useful in asthma to prevent or reverse parasympathetic stimulation of mucus

secretion and smooth muscle contraction (Gross, 1988). Inhalation of anticholinergics is effective in preventing cholinergic bronchial challenge, asthma caused by beta-adrenergic blocking agents, psychogenically stimulated asthma, and in some cases, exercise-induced asthma. Although inhaled anticholinergics are mild bronchodilators they are most appropriate in patients with chronic bronchitis and asthma. Side-effects are infrequent and consist primarily local throat irritation and dry mouth (Busse et al., 1994; Kalliner & Lemanski, 1992).

Glucocorticosteroids

Glucocorticosteroids is the most potent class of therapeutic agent available for the treatment of allergic and nonallergic inflammation associated with asthma. They alleviate symptoms in all but the most severe cases. The most important mechanisms of corticosteroid action in asthma are a reduction in the number of mucosal mast cells, restoration of beta-adrenergic responsiveness to catecholamine stimulation, and suppression of late phase allergic inflammatory reactions. Corticosteroids reduce inflammation by decreasing inflammatory cell chemotaxis, replication, survival, recruitment, and cytokine production (Holgate & Church, 1989; Kaliner & Lemanske, 1992).

The two most commonly used routes of administration of corticosteroids are inhaled and oral. Because of the increased risk of important deleterious long-term effects, the recurrent use of systemic oral corticosteroids to treat outpatient asthma is discouraged. Whenever systemic corticosteroids are used, consideration of potential side-effects and complications should be weighed against their benefits (Kaliner & Lemanske, 1992). Corticosteroids are used to reduce, reverse, or prevent the inflammation of asthma. The principle determinant of their use is to produce the desired end result with the least side effects, using enough corticosteroids for a long enough period, by the most effective route.

Several different metered-dose inhaler delivery systems for inhaled corticosteroids are available and while there are benefits and negative features of each medication, inhaled corticosteroids have distinct advantages over oral or parenteral preparations. Inhaled corticosteroids act at the site of disease and have few or no systemic or side-effects. Each agent has been engineered to reduce its bioaction once absorbed from the lungs; therefore, the topical action is far more potent than the systemic effect. However, excessive inhaled

dosages can cause some adrenal insufficiency (Holgate & Church, 1989; Kaliner & Lemanske, 1992).

Inhaled corticosteroids were initially used in therapeutic agents in conjunction with bronchodilators or to help reduce the concomitant use of oral corticosteroids. Indications for their use has broadened, and inhaled corticosteroids are typically used in chronic asthmatics who wheeze more than 2-4 days a week and/or require frequent bronchodilators, or any patient requiring episodic oral corticosteroids. In patients who have symptoms requiring inhalers two or more times a week or wheeze or cough on a daily basis, combinations of specific treatments and symptomatic control are indicated. In patients who require only intermittent therapy on order of once or twice a week, bronchodilators alone are considered to be more appropriate. Asthma exacerbated by or in conjunction with upper or lower respiratory tract infections often requires the use of corticosteroids, by either the oral or inhaled routes. Long-term use of inhaled corticosteroids can reduce airway hyper-responsiveness to its lowest point. Thus, long-term use may significantly reduce both symptoms and the need for additional drugs (Busse et al., 1994; Kaliner & Lemanske, 1992).

Oral steroids are used chronically in patients whose symptoms cannot be adequately controlled with bronchodilators and inhaled corticosteroids and acutely for exacerbations, such as may be precipitated with a respiratory tract infection, that are severe. In such patients, every effort to maintain them on alternate day regimens should be tried (Kaliner & Lemanske, 1992).

Cromolyn and Nedocromil

Cromolyn probably acts by inhibiting a variety of inflammatory cells. Cromolyn has proven useful in preventing antigen, exercise, cold air, hyperventilation, and sulfur dioxide provoked asthma. Because cromolyn inhibits lung mast cell degranulation, it prevents not only the immediate but also the late phase of the allergic reaction. This drug is useful as a prophylactic agent for prevention of mast cell related asthma, and its long-term use reduces bronchial hyper-responsiveness (Busse et al., 1994; Kaliner & Lemanske, 1992).

Although there is little published experience with treatment regimens as an index of disease severity, those that have been used have found validity and reproducibility with this approach. A scoring approach to medication use is recommended. Medication is classified into bronchodilator or anti-inflammatory. Medications are

stratified according to potency. From this approach, the severity of an individual patient has been attempted to be quantified (Busse, 1994).

One of the few examples is a scoring method used in the Veteran's Administration study of coronary bypass surgery (Peduzzi & Hultgren, 1985). In this study, the researchers employed a two-part score consisting of a severity score judging the frequency of symptoms and a medication score assigning points on the basis of use of nitrates and propranolol. The total score was the algebraic sum of the two components. These investigators found that the score was highly reproducible and correlated, although weakly, with exercise performance. The correlation with risk factors was poor and the score did not predict long-term survival in either medically or surgically treated patients, but did predict short-term survival in the medically treated group. No analysis was made of the performance of the medication component of the scale alone; did not include new cardiac medications, and did not directly address reliability.

Rossier (1994) used multivariate cluster analysis of data obtained from 128 asthmatic children to derive six severity grades of asthma. They found that higher grades of severity correlated significantly with early onset of

disease and also with greater use of interval medications. The authors discerned eight major discriminating variables, four symptoms, wheeze, cough, shortness of breath and chest tightness, and four forms of lifestyle interference, school missed, sleep missed, hospital admissions and physical activities tolerated. A 5-point scale to each of these variables was assigned and based on the total score recommendations were made for interval treatment. It is important to note that their score did not take into account use of medications in assessing severity and did not allow for the fact that lower sores, even if obtained by more aggressive interval treatment, would perhaps lead to recommendations for less aggressive subsequent therapy.

Richards, Bailey, Windsor, and Soong (1988) developed a scale to measure the intensity of regimens assessing the use of five types of medication: inhaled bronchodilator, continuous theophylline, more than two courses of steroids in the past year, another inhaled medication, and more than two courses of antibiotics in the past year. Each medication category was scored 0 to 1, depending on whether or not it was absent or present, and the overall score was obtained by summing over the five categories.

Richards et al. (1988) found that the reliability of their medication intensity scale was substantially lower than that of scales assessing respiratory symptoms, respiratory illnesses, and patient inconvenience, but was high enough to warrant use in research settings. The authors further examined the correlation of the medication intensity scale with three characteristics of asthma. The scale correlated significantly with both duration of asthma and incidence of emergency room visits or hospitalizations within the previous year, but they correlated best with physician's assessment of asthma severity.

Also, precise recommendations for asthma therapy are difficult to make because of the variability in disease severity, precipitating factors, disease chronicity, age of the patient, associated medical problems, and compliance. Methods for measuring asthma medication compliance are shown in Table 3.

Table 3

Methods for Measurement of Asthma Medication Compliance

Type of Measure	Description	Examples of Validated Instruments	Strengths of this Measurement Strategy	Weaknesses of this Measurement Strategy	Cost
Biochemical measures	Analysis of blood, urine or other bodily secretions to objectively measure medication, a medication by-product, or a tracer substance added to medication.	Theophylline assays (blood and saliva) are well validated across settings; less common assays are available for albuterol; RIA tracers/ other biological tracers have also been employed in pulmonary studies.	Direct, objective adherence measurement strategy that confirms ingestion; can provide dose-response information; useful as a nonreactive measure strategy if patients are blind to measurement.	Only available for a limited number of asthma medications; does not generally provide information about patterns of use over time; can be intrusive and burdensome if multiple venipunctures are required.	Low to moderate
Observation of MDI technique	Use of trained staff to document appropriate inhaler use.	Inhaler Use Checklist (23).	Simple, objective measurement strategy that confirms appropriate inhaler use.	Applied inhaler use skills may be different outside the clinic environment.	Low

Type of Measure	Description	Examples of Validated Instruments	Strengths of this Measurement Strategy	Weaknesses of this Measurement Strategy	Cost
Clinical judgment	Global judgments by health care providers of patients' probable adherence level.	None	Fast, simple, inexpensive; can be integrated into any clinical interaction.	Low validity and reliability unless combined with other measures, such as self-report.	Low
Self-report	Generally, interview or paper-and-pencil measures that ask patients to recall levels and patterns of medication use over a defined time.	Medication Adherence Scale (40), Inhaler Adherence Scale (23).	Fast and simple to administer; can provide detailed information about patterns of medication use, patient perception of appropriate use, and barriers to medication use; does not require patient adherence to daily record keeping.	Highly variable validity based on demand characteristics of measurement environment; limited by patient's memory.	Low

Type of Measure	Description	Examples of Validated Instruments	Strengths of this Measurement Strategy	Weaknesses of this Measurement Strategy	Cost
Asthma diaries	Daily diaries in which asthmatic patients (or parents) record medication use and symptoms; also used to record PEFR, health care use, days lost from work or school, etc.	Individualized to each study design; many asthma diaries have been validated within studies, but not validated, reliable asthma diaries have been published for general research use.	Can provide a detailed account of patient adherence to multiple medications; particularly useful for correlating medication use with triggers, such as symptoms or low PEFR; can also be used to associate daily medication adherence with asthma outcomes, such as symptoms or days lost from school; can be integrated with self-management programs.	Patient adherence to asthma diaries over time is frequently poor; asthma diary data are vulnerable to patient deceit.	Low

Type of Measure	Description	Examples of Validated Instruments	Strengths of this Measurement Strategy	Weaknesses of this Measurement Strategy	Cost
Medication measurement	Documenting the amount of medication dispensed and returned at follow-up; examining pharmacy records of dispensing patterns.	Individualized to each study design.	Relatively simple and objective measure of adherence; widely used in drug studies; can be used as an objective validation of self-report and/or asthma diaries.	Provides no information about daily patterns of medication use; dependent on patient's returning all issued medication containers; vulnerable to patient deceit; medication monitoring can be costly in staff time.	Low to moderate
Medication monitors	Electronic monitors that record date and time of medication use events, e.g., pill bottle opening or MDI actuation.	Pill monitor (Medication Event Monitoring System); MDI monitor (Nebulizer Chronolog)	Provides date and time of each medication use event, allowing long-term monitoring of adherence with detailed information about daily patterns of medication use.	Does not confirm ingestion of medication; the presence of a monitoring device may be reactive, altering natural patterns of medication use; expensive.	High

Note. Rand, C.S., & Wise, R. "Measuring adherence to asthma medication regimens," 1994 American Journal of Respiratory Critical Care Medicine, 149, pp. S70-S73. Reprinted from Severe Asthma: Pathogenesis and Clinical Management, p. 456, by courtesy of Marcel Dekker, Inc.

In designing a scale to assess asthma severity, a number of potential problems must be addressed and a major consideration in the use of medication and intensity as an index of disease severity is the question of medication compliance. Finally, Busse et al. (1994) stated that there is an inevitable circularity in attempting to quantitate medication use as an index of severity. For example, drugs that might be beneficial for a patient would be added to the regimen at a time of disease exacerbation and would likely lead to a decrease in severity of airway obstruction or bronchial inflammation; however, they would be assessed for additional points on the medication scale, leading to an assessment of increased severity.

Symptom Intensity on Existing Instruments

The severity of asthma has been characterized within epidemiological studies by symptom assessment. Symptom intensity data are among the most commonly used asthma outcome measures in clinical and epidemiologic research. However, methodological scrutiny has been limited. Instruments assessing asthma related symptoms may be considered in two groups, those suitable for ascertaining the presence of diagnosed asthma or symptoms and those

suitable for following the severity of asthma symptoms over time.

The symptoms of asthma include intermittent, reversible episodes of bronchospasm often associated with nonproductive cough, wheezing, and shortness of breath. Early symptoms are often vague, such as a heavy feeling of tightness in the chest. Also, there appears to be a subgroup of asthmatics whose asthma is characterized solely by cough without wheezing. Several instruments have been developed to help objectify a patient's subjective perception of symptoms such as wheezing, chest tightness, dyspnea, cough, and sputum production. It should be noted, however, that the physical findings of asthma vary over time and maybe normal between episodes. Though they may correlate with the severity of a given episode, they do not correlate with the severity of the disease as a whole in a given individual.

Questionnaires designed to detect asthma in epidemiologic studies are generally designed for one time administration and usually are focused on symptoms that have ever occurred in the subject's life or that have occurred over the last 1 to 2 years. They provide limited data to permit quantifying the severity of asthma with precision, and they have not been used or evaluated in

terms of responsiveness to clinical intervention. Their utility is in establishing the prevalence of asthma in populations, screening for asthma in the workplace, studying potential etiologic risk factors for asthma, and providing a standardized procedure for screening subjects for possible enrollment in clinical trials of asthma therapy (Lehrer et al., 1992).

The Medical Research Council questionnaire (MRC) was designed primarily for detecting the presence or absence of chronic bronchitis or other lung disease, including asthma, in epidemiologic surveys (O'Connor & Weiss, 1994). The range or responses concerning symptoms relevant to asthma is quite limited. For example, wheeze may be reported as none, any or chronic. Many aspects of asthma symptoms are not specifically addressed. Gradients of cigarette smoking history and pulmonary function measurements across categories of symptom responses have supported the validity of the questionnaire items as measures of respiratory disease. Questions on asthma, morning sputum production, chest tightness, and wheeze have high validity against the criterion of concurrently measured methacholine airway responsiveness.

The American Thoracic Society, Division of Lung Disease (ATS-DLD) questionnaire was designed principally

for ascertaining the presence of chronic lung disease, including asthma. As with the MRC questionnaire, the range of possible responses regarding symptoms relevant to asthma is narrow for following the status of patients with established diseases. Gradients of pulmonary function and smoking histories across symptom-response categories have been shown. Positive responses to questions about asthma-related wheezing have been shown to be associated with increased nonspecific airway responsiveness.

Instruments suitable for following the severity of asthma symptoms over time require a short reporting interval as well as detailed information on intensity, duration, and frequency of symptoms. Janson-Bjerklie (1992) found that adults with asthma make independent self-assessments that generally correlate with objective markers of severity. This group of researchers developed an Asthma Severity/Risk Index to evaluate the overall severity of asthma. Though such scales have been widely employed in clinical trials and are adequate for ascertaining the presence of asthma, they have not received sufficient methodological scrutiny for evaluating symptomatic severity (O'Connor & Weiss, 1994).

In one of the largest longitudinal population based studies of asthma prevalence, the Tucson Epidemiologic

Study of Obstructive Lung Diseases, Lebowitz et al. (1975) examined a multistage stratified cluster sample of white Tucson households. Thought the rates of severe asthma were not specifically defined, 11.9% of men and 6.4% of women reported the presence of wheezing on most days. Thirty-two percent of subjects were graded as severe based on symptoms of wheezing on most days.

Clinical investigators have employed many different methods of obtaining and analyzing symptom data in clinical trials. Many of these methods have involved symptom scores or scales that were clearly responsive to the therapies being studied, however, very little methodological data are available addressing the reliability and validity of these instruments. The following instruments reviewed represent those published in clinical trials.

The Denver Asthma Symptom Checklist was designed to measure the symptoms perceived during asthma attacks to determine whether the pattern of these subjective perceptions helps predict the ability of asthma patients to cope with their disease and engage in self management. This instrument does not measure the frequency or severity of asthma symptoms. Its reliability and validity against the criterion of concurrent physiologic measurements have

not been studied. The score of the panic-fear scale is significantly correlated with asthma severity as judged by a physician, and the scores of the panic-fear and airways obstruction scales show limited correlation with health care utilization, including repeat hospitalization after discharge.

The University of Alabama at Birmingham's Comprehensive Asthma Program Scale was designed for broad applicability to epidemiologic and clinical research. These scales have been employed in an interview format, but have been designed to be suitable to epidemiologic and clinical research. While these scales are employed in an interview format, they have been designed to be suitable for incorporation in written questionnaires. The five scales relevant to asthma outcome include occurrence and severity of recent symptoms, frequency of recent episodes of respiratory illness, inconvenience scales, intensity of medication regimen required, and occurrence and severity of medication side-effects.

The broad range of responses on each of these scales makes them suitable for clinical studies of patients of asthma. All five scales show significant correlations with asthma severity as judged by a physician and with reported emergency room visits or hospitalizations for

asthma in the past year, correlations which help validate these scales. Side-effect scores were highest for theophylline and oral corticosteroid use, which suggests validity of the medication side-effect scale. Validity of these scales against concurrently measured pulmonary function level, pulmonary function variability, or nonspecific airway responsiveness has not been reported. Responsiveness to these scales to intervention has been demonstrated to a limited degree.

The University of Cincinnati disease severity score and airway reactivity score was designed to quantify both the disease severity and airway hyper-responsiveness of patients with chronic stable asthma on the basis of the questionnaire response (Brooks, 1990). Disease severity score is the sum of six individual items scores reflecting the patients estimate of his or her average clinical status during the past 6 months. The items include number of asthma attacks requiring physician treatment, frequency of wheezing or chest tightness on an average day, frequency of wheezing or chest tightness on an average night, cough, on an average day or night, usual degree of shortness of breath, and medication use. In a study of 24 selected asthma patients, the disease severity score and airway reactivity score were highly correlated with each

other and with the methacholine airway responsiveness. The repeatability of these scores and their responsiveness to therapeutic interventions have not been demonstrated.

Other types of instruments assess the perception of symptoms among asthmatics as a measure of quality of life and a possible determinant of medication use during self-management. The Asthma Symptom Profile (ASP) is a tri-dimensional scale assessing phasic changes in asthma symptoms. The three dimensions are: intensity, unpleasantness, and quality of sensations. Although this scale overlaps in some ways with measures of dyspnea by Mahler and Harver (1990), the assessment of asthma symptomatology is not precisely the same as assessment of dyspnea. In addition to shortness of breath, asthmatics describe such sensations as stridor and a need to cough, and none of the existing scales assess the emotional component of asthma symptoms. Although very useful (Kinsman et al., 1982), it is sensitive to the multidimensional nature of asthma symptoms and designed to assess changes in symptoms occurring over the course of weeks, rather moment to moment (Lehrer et al., 1993).

Verbal descriptors of the ASP were gathered from 46 adult asthmatics for each of the three scales, using bimodality scaling. The ASP was analyzed before and after

bronchodilator in 44 asthmatics using ipratropium bromide. Forty of these subjects were also tested in a placebo condition. Although ASP changes produced by ipratropium bromide were no greater than those produced by the placebo, correlations with changes in spirometry variables were significant. The ASP appears to be a useful measure of phasic changes in asthma symptoms. Asthmatics with mild airway obstruction do not appear to be able to discriminate small changes in airway function. Reliability scores were not reported (Lehrer et al., 1993).

Quantification of ordinarily-used verbal descriptions of the asthma experience can be done in any of several modalities, for example assigning numerical value to a verbal descriptor as used by Borg (1982); or engaging in other quantifiable activities that could correspond to the perceived magnitude of a descriptor, such as drawing lines of varying lengths. Multimodality assessment is considered preferable in psychophysical scaling (Cross, 1982). Such an approach would give verbal descriptors the statistical properties of a ratio scale. This strategy has been used by Turkey and his colleagues in their Pain Perception Profile (Turkey et al., 1982).

Ideally, a symptom questionnaire or symptom scale should be able to discern the episodic nature of symptoms and quantify the intensity, duration and frequency of symptoms. In addition, the validity of such instrument with respect to concurrent physiologic measurements and its repeatability should be established. If an instrument is to be used to study the efficacy of an asthma therapy, then the responsiveness of the instrument to intervention should be established (Epstein & Sherwood, 1996).

Functional Status and Existing Instruments

The status of an individual's function represents the impact of asthma on one's ability to perform age-appropriate activities under a broader range of circumstances. This aspect of severity is very important to how patients perceive their lives. Psychological, sociological, and physiological factors all mediate perception of functioning. Therefore, people with equal physiological impairment may vary widely in the level of functional impairment they experience (Stein, 1987).

Two basic types of instruments are used to evaluate functional status in patients with asthma. Generic instruments such as the Index of Activities of Daily Living, the Sickness Impact Profile, the Rand Insurance

Study, the Impact on Family Scale, and the Rand Medical Outcome Study SF-36 are general purpose measures of health status that can be used for many disease states. They may be expected to yield some information about the overall effects of asthma on functional status (Rothman et al., 1993). Juniper (1992) and Hyland (1991) have developed asthma-specific instruments that may be more responsive to asthma-related changes in health status than their generic counterparts. Emerging consensus indicates that both types of instruments have important advantages and should, therefore, be used concurrently in research studies (Lohr, 1989; Richards et al., 1994; Rothman et al., 1992).

Some epidemiological studies have included measures of severe asthma from a functional severity standpoint. Rossier and colleagues identified the prevalence of severe asthma in an Australian population sample. They surveyed 10,000 randomly selected Melbourne school children. Of the respondents, 14% reported a history of asthma in the past year, and 4.4% reported severe asthma based on a functional severity score that included the dimensions of physiological and functional severity.

Insight into the relationship between functional status and severe asthma can be gained by examining the few published clinical trials that have used this measure

to study persons with severe asthma. Quirk (1991) studied 124 persons with asthma recruited from six countries. They found a statistically significant correlation between FEV_1 and 15 of the 76 questions regarding the effect of asthma on their everyday lives. This suggests that some overlap exists between the domains of functional status and physiological intensity. While there is a growing development of functional status measurement in asthma, there are a few current data to fully characterize this population.

Well-Being and Existing Instruments

Most studies of well-being and quality of life have involved chronic or life-threatening diseases with a significant and continuous impact on the quality of life (Richards et al., 1994). In diseases such as cancer, the issue is often whether chemotherapy, a treatment with significant effect on the quality of life, will improve a patient's overall quality of life. Asthma, in contrast, is a disease characterized by episodes of severe symptoms separated by periods when the patient is relatively symptom free. The treatment of asthma is relatively benign and has a small effect on quality of life. Studies of quality of life in asthma focus on determining which

treatment most improves the patient's quality of life. Therefore, research instruments designed to evaluate quality of life may be less appropriate for use in patients with asthma (Richards & Hemstreet, 1994; Rothman et al., 1992).

The Saint George's Hospital questionnaire was designed to quantify the impact of asthma and chronic airflow obstruction on health and well-being (Jones, 1992; Quirk, 1991). It is a 76-item questionnaire that includes questions about the presence and severity of symptoms, restrictions of physical activity, and subjective impact of symptoms and restricted activity on quality of life. Questions relate to symptoms during the past year. Validity against the criterion of concurrently measured airway function has not been reported. Two-week repeatability of the overall score appears good. Responsiveness to therapeutic or exacerbating factors has not been reported.

Marks and colleagues (1992) designed and validated the Asthma Quality of Life Questionnaire. Items in this questionnaire assess the degree of breathlessness, mood, concerns about health, and social functioning. After internally validating the instrument, the researchers examined the relationship between the functional status

measures and several traditional medical measures of asthma severity, FEV_1, $PD20FEV_1$ and number of drugs per patient. They found only correlation's in a community sample of subjects with asthma, suggesting that quality of life and functional status represent a separate dimension of asthma severity.

Several other studies support this contention. Juniper and colleagues (1993) studied a single cohort of subjects for an 8-week period. At each visit, the Asthma Quality of Life Questionnaire, the Sickness Impact Profile, and a shortened version of the Rand General Health Survey were administered along with spirometry. In addition, airway responsiveness to methacholine was measured. At the study's conclusion only a very weak correlation was found between the measures of quality of life and medical measures of asthma severity.

Summary

Most phenomena of interest, like disease severity, to researchers are dynamic in nature and only by understanding severity in all of its dimensions will the burden of asthma be estimated. Most clinicians rely on information about patterns of disease severity to understand and treat disease. Understanding an asthmatic's pattern of disease expands knowledge of

clinical science and provides clinical indicators of treatment effectiveness. However, in designing an instrument to assess asthma severity, a number of potential problems must be addressed.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

This methodological study sought to increase knowledge and insight regarding the character of asthma through instrument development and testing. Although a variety of instruments measure disease severity, no consensus exists in the literature nor has the theoretical process of the character of asthma been described.

In the development of the theoretical domain of the character of asthma, a methodological study design is necessary (Brinberg & McGrath, 1985). Methodological designs enable critical examination of instruments developed to measure a phenomenon (Burns & Grove, 1993). Such analyses of instruments involve the measurement of reliability and validity. Thus, a methodological study design generates information regarding the accurate measurement of the character of asthma (Waltz et al., 1991).

Instrument

The Asthma Outcome Index (Appendix E) was used to gather data. The eight subscales included were the "Symptom Intensity G Scale," the "Symptom Intensity B Scale," the "Management Intensity Scale," the "Functional Status Scale," the "Environmental-Impact Scale," the "Somatic Vulnerability A Scale," the "Somatic Vulnerability B Scale," and the "Medication Management Intensity Scale." The demographic section gathered descriptive information to describe the study sample and to allow future comparison across studies.

In the development of the Asthma Outcome Index (AOI), a preliminary step was a review of the literature relevant to the conceptualization of the construct. A detailed examination of conceptual and methodological issues focused on existing instruments. The project evolved from discussions during an asthma task force meeting discussing emergency room utilization of asthmatics, cost of care, and asthma education programs. Concerns voiced by members of this task force included how to evaluate outcomes following the completion of an asthma education program. Needed was baseline data identifying the character of asthma for each patient and a measurement to evaluate interventions. From an identified need to evaluate

outcomes came an attempt to measure reliably and hopefully predict the changing character of asthma as patients are seen in the Emergency Department and followed in the Asthma Clinic.

Inquiry related to the character of asthma from physicians and patient focus groups explored intuition, ideas, and known theories. Concept operationalization involved conceptual mapping, formulating variable definitions, identifying variable dimensions and observable indicators. Once the original instrument with five subscales was concluded, the instrument was submitted to content experts for evaluation and pilot tested. Following pilot testing and content expert evaluation, the scales collectively known as the AOI was revised with eight subscales and prepared for the present (major) study.

Pilot Study and Content Expert Evaluation

An original instrument was constructed utilizing a question and answer type format. Once the AOI development was concluded, the instrument with five subscales was pilot tested. A pilot study was undertaken for three reasons. The first was to gain information from local content experts and focus groups regarding the adequacy of

items on the theoretically defined subscales. A second reason was to gain feedback from local experts about the thoroughness, readability, and clarity of items. Content experts assessed how well the items represented the character of asthma and the theoretical definitions of concepts. Pilot participants and focus group members evaluated the ease or difficulty in completing items. Finally, the pilot study was conducted to obtain data for statistical analysis related to beginning reliability and validity assessment of the instrument.

Setting

The setting for data collection was a 940-bed, publicly supported hospital with an affiliated medical school in the southwest. People diagnosed with asthma were seen in an outpatient clinic. Participants were approached and informed that the purpose of the pilot study was to evaluate the effectiveness of an instrument. The instrument was given to people with asthma indicating an interest in participating in the study.

Subjects

Subjects for the pilot study included 50 male and female patients between the ages of 18 and 60. Demographic data for the pilot study participants are

presented in Table 4. The pilot sample was equally distributed between whites and blacks (44%), predominantly female (80%), with a mean average age of 41.3 years.

Table 4

Demographic Data of the Pilot Sample

Variable	Frequency	Percent
Gender		
Male	10	20.0
Female	40	80.0
Ethnicity/Race		
Black	22	44.0
Hispanic	2	8.0
Native American	2	4.0
Asian	0	0.0
White	22	44.0
Education		
Some high school	7	14.0
High school graduate or GED	13	26.0
Technical or Trade School	0	0.0
Some College	17	34.0
College Graduate	8	16.0
Post-graduate Study	5	10.0
Household Income		
< $15,999	2	4.0
$16,000-$29,999	25	50.0
$30,000-$49,999	7	14.0
$50,000-$79,000	10	20.0
> $80,000	6	12.0
Length of Time with Asthma		
< 1 year	11	22.0
1-5 years	10	20.0
6-10 years	4	8.0
11-20 years	14	28.0
21-30 years	6	12.0
> 30 years	5	10.0

Variable	Frequency	Percent
Onset of Asthma		
10 years old	13	26.0
10-19 years old	4	8.0
20-29 years old	7	14.0
30-39 years old	13	26.0
40 years or older	13	26.0

Reliability

Reliability is the accuracy or precision of a measuring instrument (Kerlinger, 1986). The question asked is, "Is this instrument dependable, stabile, consistent, predictable and accurate?" (Kerlinger, 1986, p. 404). Further, Kerlinger (1986) stated reliability is the proportion of the "true" variance to the total obtained variance of the data yielded by a measuring instrument. It is the proportion of error variance to the total variance yielded by the instrument subtracted from 1.00 with an index of 1.00 being perfect reliability. Skewed and kurtotic scores resulting in less variance lower coefficient alphas.

In the pilot study, the scales of the AOI were evaluated for internal consistency reliability using Cronbach's coefficient alpha and Kuder-Richardson formula 20 (KR 20). Waltz et al. (1991) stated internal consistency reliability is the preferred index and

measures the extent to which performance on any one item of an instrument is a good indicator of performance on any other item in the same instrument. The estimation of internal consistency is considered important before an instrument, either original or modified, is used for research purposes. To compute Cronbach's alpha and K-R 20 for the pilot study, the reliability procedure was performed using SPSS-X software.

A coefficient alpha was executed on each scale, except the Self-Management Scale. Kuder-Richardson formula 20 (K-R 20) was executed on the Self-Management Scale. The K-R 20 is used when data are dichotomous. Alphas for the subscales were: 0.7946 for Symptom Intensity, 0.8862 for Self-Management, 0.7372 for Medication Management Intensity, 0.8942 for Somatic Vulnerability, and 0.8169 for Physiological Intensity (Table 5). The alpha coefficients were considered strong for a newly developed instrument.

Subscales of the Pilot Study

Symptom Intensity Scale. This scale provided data to evaluate the degree of wheezing, shortness of breath, cough, chest tightness, fatigue, irritability and nervousness on good, typical days and on bad, atypical days. This scale also asked questions about nocturnal

awakenings. As the scale was summative the item-to-scale correlations ranged from 0.468 to 0.790. No items were deleted and these sixteen items afforded a possible score range from 0 to 48. The higher the score the more intense the symptoms exhibited by the patient. The alpha coefficient for this scale was 0.7946.

Table 5

Initial Alpha Correlation Coefficients for Five Subscales

Subscale	No. Items	Alpha
Symptom Intensity	16	0.7946
Self-Management	41	0.8862
Medication Management	14	0.7372
Somatic Vulnerability	26	0.8942
Physiological Intensity	15	0.8169

Self-Management Scale. This scale contained factually-stated items addressed as "yes" or "no." Questions asked respondents to identify their sensitivities and exposures to allergens and their management techniques in the care of their asthma. The scale was summative and the item-to-scale correlations ranged from 0.272 to 0.764 for this 41-item scale. The scores ranged from zero to 41. A high score demonstrated

patients' recognition of allergens and current management techniques. No items were deleted and the alpha coefficient was 0.8862.

Somatic Vulnerability Scale. The 26 items included in the original "Somatic Vulnerability Scale" were items 49, 50, 51, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, and 73. Using a Likert Scale responses formulated a 2-point response for always true, 1 point for sometimes true, and zero points for not true. Negatively worded items were recoded. The scale was summative with a range of zero to 78 with item-to-scale correlations from 0.332 to 0.798. Patients with high scores were more predisposed to asthma exacerbations. No items were deleted. Alpha correlation coefficient for this scale was 0.8942.

Medication Management Intensity Scale. Instructions read, "Please list all the medicines you take for your asthma, please include when you take them and how much." The responses formulated a two to five point format dependent on type of medication listed and frequency. The scale was summative with a range of zero to 35. The higher the score the more medication taken by the patient

to control asthma. The item-to-scale correlations were 0.030 to 0.618. The alpha coefficient was 0.7372.

Physiological Intensity Scale. The 15 items included in the original "Physiological Intensity Scale" were items 8, 15, 16, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, and 85. Co-morbidities, number of years with asthma, and number of hospitalizations, intubations, and emergency visits to the hospital were some of the items evaluating underlying disease intensity. The higher the score the worse the intensity of the disease. This was a summative scale with a range of two to 37. Item-to-scale correlations were 0.333 to 0.879. No items were deleted. The alpha coefficient was 0.8169.

Content Validity

Content validity asks the question, "Is the substance or content of this measure representative of the content or the universe of content of the property being measured?" (Kerlinger, 1986, p. 17). Content validity, defined by Cronbach (1972), pertains to whether the set of items adequately covers the content domain of interest, as well as the set of behaviors implied by the scores. Content validity consists of a judgement whether the instrument samples all the relevant or important content

or domains. Waltz et al. (1954) calls this approach to validation "validity by assumption," meaning the instrument measures what it says it measures because an expert says it does. Furthermore, items not related to content introduce error (Streiner & Norman, 1995).

Content Experts

Content validity was evaluated when the instrument was given to experts in the field to review. These experts included a board certified Allergist, board certified Emergency Medicine and Pulmonary physicians, a nurse practitioner and respiratory therapist (Appendix D). Five experts agreed to evaluate the instruments for content validity. Four returned usable packets.

Evaluation Criteria

The item pool within each domain was sent to content experts. Each expert was provided a copy of the objectives, table of specifications, and the instrument. The expert judges assessed whether the content domain was adequately assessed.

A numerical value reflecting the level of content-related validity evidence was obtained by using the index of content validity (CVI) developed by Waltz and Bausell (1981). Using the instrument, experts rated the content

relevance of each item using a 4-point rating scale: 1 = not relevant; 2 = unable to assess for relevance without item revision or item is in need of such revision that it would no longer be relevant; 3 = relevant but needs minor alteration, and 4 = very relevant and succinct. In addition to evaluating existing items, the experts were asked to evaluate readability, possible offensiveness of language and important areas not included in the instrument. Items which three of the four experts judged as 3 = relevant but needs minor alteration or 4 = very relevant and succinct were considered content valid items within the domain of interest (Lynn, 1986). Items that did not achieve minimum agreement by the expert panel were revised. Suggestions by experts included adding additional questions regarding the functional status and well being of subjects. No items were deleted.

Face Validity

Face validity asks the question, "Do the items appear on the surface to be measuring what they actually are?" (Streiner & Norman, 1995, p. 58). If an item appears irrelevant, then the respondent may very well object to it or omit it, irrespective of its psychometric properties. However, face validity does not provide evidence for

validity, that is, that the instrument measures what it purports to measure (Waltz et al., 1991).

A physician focus group with Allergists and a primary care physician reviewed latent variables and their position to each other in a model. Input was given regarding types of questions needed per concept. Follow-up discussions with these physicians included the revision and formalization of questions. The Asthma Clinic staff focus group included nurses, a pharmacist, and a respiratory therapist. Their evaluation addressed readability and delivery of instrument to patients. Staff was able to assist the patients with ease in completion of the instrument. Recommended changes made the instrument concise and comprehensive enough to be completed in 20 minutes or less with most adults.

A patient focus group was held during an Asthma Clinic session. Patients were asked open-ended questions. Readability, comprehension, and completeness were assessed. One patient volunteered to read each question and discuss what each question meant to her and what her answer meant. This focus group provided assistance in improving the instrument.

Changes in AOI and Readiness for Major Study

In response to content expert suggestion and follow-up dialogue sessions, the revision of the original instrument included the addition of 11 items. These 11 items represented questions about functional status and well being. Additional recommendations from experts included changing the original instrument from a five scale to eight scale instrument. The recommended changes included dividing the "Symptom Intensity Scale" and the "Somatic Vulnerability Scale" into two subscales. Measuring sensitivities and exposures to aeroallergens and environmental allergens as a separate scale and including functional status questions in scale format. The "Physiology Intensity Scale," was deleted and questions were used as descriptors. Finally, the "Self-Management Scale" was renamed the "Management Intensity Scale."

Major Psychometric Study

The purpose of the major psychometric study was to further develop, refine, and estimate the psychometric properties of the Asthma Outcome Index (AOI). Following is a description of the design of the study, including population and sample selection criteria. Also included is the method of data collection and data analysis for the study.

Population and Sample

A purposive sampling technique was employed to locate the sample participants. Purposive sampling involves the conscious selection by the researcher of certain subjects or elements to include in the study until the desired sample size is reached (Burns & Grove, 1993). Although potential for bias exists in this sampling type, serious bias is not necessarily present in the sample. In order to allow for comparison of the sample with the target population, as much data as possible should be collected and reported about the sample.

McGrath and Brinberg (1983) stated that sampling plays a crucial and complex role in external validity, the robustness of research findings, or the ability to generalize the findings of a study. They contend there are at least four major sampling strategies that might be adopted for a study. These include: (a) sampling homogeneously over the entire study; (b) sampling several subsets, each homogeneous within subset but differing between subsets, so that all subsets together span the whole range; (c) sampling heterogeneously, but in a way that yields an overall distribution among the cases within the study that is reflective of the distribution of the real world; and (d) sampling heterogeneously without

regard to representativeness. McGrath and Brinberg (1983) point out that these four strategies offer different opportunities for exploring robustness for any given set of findings. McGrath and Brinberg support a selective approach of choosing a homogeneous sample as more useful when the researcher is explicitly searching for boundary conditions on theoretically predicted hypotheses.

Lynch (1983) contended that when a researcher has no formal theoretical (explanatory) grounds for predicting an outcome on a variable, the selective approach of homogeneous sampling would be preferable to deliberate sampling for heterogeneity because interaction or relationships can be interpreted more easily. With a desire to assess aspects of robustness or external validity in this research study, the decision was made to select a homogeneous sample.

The sample chosen was as representative as possible to allow generalization. As for the size of the sample, EQS 5.1 an application of structural equation modeling is a large-sample method and recommends the larger the sample the better (Bollen, 1993; Jöreskog & Sorbom, 1993). Pedhazur and Schmelkin (1991) stated that for the Chi-Square Test to be valid, it is assumed that the sample

size is sufficiently large. However, there is no agreement about the meaning of "sufficiently large."

Boomsa (1985) recommended that a sample size of at least 200 be used in factor analytic studies. Tanaka (1987), on the other hand pointed out that unlike the situation in multiple regression analysis where sample size is formulated with regard to the ratio of the number of subjects to the number of variables, in SEM, the ratio of concern is that of the subjects to the number of estimated parameters. Furthermore, Tanaka (1987) noted that recent developments in latent variable models make fewer assumptions about the distribution of the data and allow for data nonnormality, therefore requiring a larger sample than the more standard methods such as maximum likelihood and generalized least squares.

Jöreskog and Sorbom (1993) recommended three formulas for determining an adequate sample size for SEM analyses. If K is the number of input variables or indicators, the formulas are:

$k(k+1)/2$ when computing correlation matrices;

$k(k+1)/2$ when computing covariance matrices; and

$(k+1)(k+2)/2$ when computing asymptotic covariance matrices.

For this study a correlation matrix was computed where k is the number of indicator variables. A sample of 203 was considered adequate using all of the above criteria.

Protection of Human Subjects

The study used the researcher's developed instrument. The study complied with all the rules and regulations of the Human Subjects Review Committee of Texas Woman's University, University of Texas Southwestern Medical School, and Parkland Memorial Hospital. All subjects were approached by the researcher. Each participant, whether previously known to the researcher or not, was free and capable of choosing to participate. Informed consent was obtained from all subjects verbally, and in writing after reading a written explanation of the study requirements in the form of a letter outlining the purpose, potential benefits, and alternatives. The name, address, and office telephone number of the researcher were listed in the letter. Each subject was given a copy of the consent form. A statement indicating availability of the researcher to answer questions or concern prior to, during, and after post study was included.

Participation in the study was confidential. Confidentiality of the data was maintained by using a study code and was kept in a locked office. All data

analysis was in summary form with no identifiers. Benefits from participation included the possibility of increased awareness of one's health status related to asthma. No permanent discomfort or harm was anticipated from responding to the instrument.

Data Collection

After having been purposively selected to the sample, the prospective participant was contacted to establish willingness of the person to participate in the study. If agreement was obtained, the subject was asked to sign a consent form and complete the instrument. The researcher evaluated the instrument for completeness and assisted subjects on those items that the subject did not respond or complete.

Treatment of Data

Following the data collection, data were coded and entered into a computer data file. Using EQS for Windows 5.1 (Biomedical Computer Program P series) frequencies and percentage distributions on demographic information were obtained. The data were analyzed for internal consistency (reliability) and factor loadings (construct validity), thereby testing the theoretical framework and measurement

model. Following are study hypotheses with their specific data treatments and specified criteria:

H1. The estimated degrees of homogeneity of items and scales for the AOI are greater than a Cronbach alpha coefficient of 0.70 in persons with asthma.

Reliability for each subscale was determined using Cronbach's alpha coefficient or Kuder-Richardson formula 20. Internal consistency refers to the extent to which all items on a scale measure the same concept (Kerlinger, 1986). Support for internal consistency would be demonstrated by alpha correlation coefficients of 0.7 or greater on each subscale. The higher the alpha correlation coefficient, the higher the reliability of the instrument. While alpha correlation coefficients of 0.8 to 0.9 are desirable, it is expected that a newly developed instrument would estimate internal consistency somewhat lower (Nunnally, 1978).

Reliability is of concern in research where indicators are designed to measure effects of latent variables. The most commonly used reliability coefficient is Cronbach's alpha coefficient. Bollen (1989), however, stated that coefficient alpha does not make allowances for correlated error or the effects of more than one latent variable on any observed variable. In structural equation

modeling, measure of reliability of indicators is squared multiple correlation. The squared multiple correlation coefficient is defined as reliability coefficient that is the magnitude of the direct relations that all variables have on indicators. This coefficient ranges from zero to one, with values closer to one indicating higher reliability (Bollen, 1989; Jöreskog & Sorbom, 1989).

H2. The theoretical measurement model for asthma demonstrates a statistical fit to the observed data.

Construct validity is dependent on a conceptual or theoretical base for a study. If an instrument has construct validity, the instrument represents the conceptual or theoretical concepts. As a beginning assessment of validity, the AOI was factored by using exploratory factor analysis. Exploratory factor analysis employed both principal components analysis and alpha factoring, each with oblique and orthogonal rotation. Confirmatory factor analysis was used to evaluate the measurement model. Using the maximum likelihood method, the hypothesis tested was that the measurement model derived a good fit with the population. Because statistical significance would indicate a difference between the measurement model and the population a desired result was a non-significant chi-square.

Summary

This chapter detailed the development of the Asthma Outcome Index, a research instrument designed to measure the character of asthma. Methods for the estimation of validity and reliability were presented. Content validity was supported by a panel of content experts. A pilot study was conducted with 50 people diagnosed with asthma. The alpha correlation coefficients for the original instrument were favorable, providing preliminary evidence of internal consistency.

Statistical analysis and participant feedback of the pilot test as well as the content expert evaluation was used to revise the original instrument. Procedures for the psychometric study of the revised instrument for sample selection, administration of the instrument, and collection and treatment of data were described. Use of confirmatory factor analysis following an exploratory factor analysis was supported.

CHAPTER IV

ANALYSIS OF DATA

The purpose of this study was to develop a valid and reliable instrument to measure the character of asthma in adults. The data were analyzed through a series of statistical and analytic procedures termed structural equation modeling (SEM). Data analysis findings will be described in detail, and each hypothesis examined in the light of the findings.

Description of the Sample

The number of subjects for this study was 203 adults with asthma between the ages of 18 and 60 residing in southwestern United States. The mean age was 42, with all years between 18 and 60 represented, and more than half were between 36 and 55 (62%). The data were collected over a period of 6 months. Preliminary data screening indicated that the sample was skewed with respect to several demographic characteristics. For example, the majority of the subjects were women (82%), belonging to a minority group (82%), and having incomes below $29,999 (87%). They received treatment for asthma in the

Emergency Department (80%) and had prescriptions filled in the hospital pharmacy (97%). Additional descriptive data, including age, gender, race/ethnicity, employment status, income level, educational level, number of children living in the home under the age of 16, type of health care payment, and where they get prescriptions filled are presented in Table 6.

Demographic data included the length of time of diagnosis, age of onset, history of bronchitis, treatment areas for asthma during the year, place of treatment for last asthma attack, and types of physicians caring for their asthma. Further descriptive data included the perception of the amount of educational information received from doctor or staff; number of Emergency Department visits, hospitalizations, and intubations; forced expiratory volume (FEV1) readings; co-morbidities; smoking history and whether they lived or worked with people who smoke.

Subjects reported taking an average of four medications per day for their asthma and considered the status of their disease to be about the same or somewhat worse than a year ago. A 15-point visual analog scale, asking how they felt about their quality of life at that

moment, scored a mean of 8 with 0 being the poorest and 15 being the best.

Table 6

Descriptive Data of Research Sample

Variable	Frequency	Percent
Mean Age: 42.45 years		
Gender		
Female	166	81.8
Male	37	18.2
Ethnic Background/Race		
Asian	9	4.4
Black	100	49.3
Hispanic	37	18.2
White	57	28.1
Education Level		
Some High School	70	34.5
High School Graduate or GED	49	24.1
Technical or Trade School	16	7.9
Some College	47	23.2
College Graduate	17	8.3
Post-Graduate Study	4	2.0
Employment		
Yes	117	57.6
No	86	42.6
Family Income per Year		
< $15,999	147	72.4
$16,000-$29,999	29	14.3
$30,000-$49,999	12	5.9
Preferred not to answer	15	7.4

Variable	Frequency	Percent
Type of Health Care Payment		
Self-pay (no insurance)	101	49.8
Medicaid	23	11.3
Medicare	28	13.8
Health Insurance	19	9.4
Don't Know	32	15.7
Number of People Residing in Household		
1	30	14.8
2	50	24.6
3	31	15.2
4	51	25.1
5	27	13.3
6	4	2.0
7	5	2.5
8	2	1.0
9	2	1.0
10	1	0.5
Number of Children Residing in the Household Under Age of 16		
0	95	46.8
1	42	20.7
2	36	17.7
3	19	9.4
4	8	3.9
6	1	0.5
9	2	1.0
Where Prescriptions are Filled		
Private Pharmacy	7	3.4
Hospital Pharmacy	196	96.6
General Statement Regarding Health		
Excellent	2	1.0
Very Good	11	5.4
Good	49	24.1
Fair	108	53.2
Poor	33	16.3

Variable	Frequency	Percent
Comparison of Health to 1 Year Ago		
Much Better	36	17.7
Somewhat Better	27	13.4
About the Same	67	33.0
Somewhat Worse	63	31.0
Much Worse	10	4.9
Length of Time Having Asthma		
< 1 year	16	7.9
1-5 years	49	24.1
6-10 years	25	12.3
11-20 years	34	16.3
21-30 years	29	14.3
> 30 years	50	24.6
Age of Onset of Asthma		
< 10 years old	72	35.5
10-19 years old	18	8.8
20-29 years old	25	12.3
30-39 years old	42	20.7
40 years or older	46	22.7
History of Bronchitis		
Yes	97	47.8
No	106	52.2
Treatment Areas for Asthma during the Year		
In an Emergency Room	162	79.8
In a Doctor's Office or Clinic	117	57.6
Over the Telephone by a Doctor	12	5.9
Overnight Treatment in a Hospital as a Patient	49	24.1
Treated Self at Home	100	49.3
Primary Treatment Site for Last Asthma Attack		
In am Emergency Room	139	68.4
In a Doctor's Office	6	3.0
Over the Telephone with a Doctor	0	0.0
In the Hospital as a Patient	17	8.4
Treatment Myself at Home	41	20.2

Variable	Frequency	Percent
List All Types of Physicians Caring for Asthma		
Allergist	91	44.8
Family Practice Physician	66	32.5
General Practice Physician	79	38.9
Internist	32	15.8
Pediatrician	18	8.9
Pulmonologist	52	25.6
Amount of Information Received from Doctor or Staff		
Given very little information	11	5.4
I could use more information	85	41.9
I have everything I want to know	107	52.7
Status of Asthma over the Past Year		
Gotten better	49	24.1
Stayed about the same	83	40.9
Gotten worse	71	35.0
Number of Times for Emergency Dept. Visits during the Last Year		
None	26	12.8
1-2 visits	73	36.0
3-5 visits	59	29.1
> 5 visits	45	22.1
Number of Intubations in a Lifetime		
Never	73	36.0
Once	45	22.2
2 or more times	85	41.8
FEV1 (baseline)		
> 80% predicted	48	23.7
< 80% predicted	77	37.9
< 60% predicted	66	32.5
< 40% predicted	12	5.9
Live with People Who Smoke		
No	123	60.6
Yes	80	39.4

Variable	Frequency	Percent
Co-morbidities		
None	105	51.7
Heart Disease	11	5.4
Diabetes	17	8.4
Hypertension	47	23.2
Other	23	11.3

Findings

The data analysis findings are presented in four parts. First, an exploratory factor analysis and exploratory data analysis on instrument items with identification of eight subscales is presented. Secondly, internal consistency of the eight subscales is presented using coefficient alpha or Kuder-Richardson formula 20. Third, a factor analysis of the 8 new subscales with the development of the measurement model is presented. Finally, the confirmatory factor analysis and the two hypotheses will be discussed in the areas of reliability and validity.

Exploratory Factor Analysis

If an instrument has a number of scales, like the Asthma Outcome Index, two analytic techniques are possible. The first is an item-scale total correlation in which the item is correlated with its scale total. The

second technique is an exploratory factor analysis in which items can be described in terms of a smaller number of underlying factors (Streiner & Norman, 1995).

Exploratory factor analysis employed both principal component analysis and alpha factoring, each with oblique and orthogonal rotation. An initial principal factor analysis specified 22 factors. Analyses failed to delineate extractable, theoretically logical factors. This is not unexpected in item pools developed as summative measures for a single construct (Nunnally, 1978) and use with dichotomous items can lead to quite anomalous results (Comry, 1978).

Exploratory Data Analysis

Exploratory data analysis using EQS for Windows 5.1 (Biomedical Computer Program, P-Series) examined data for normality, outliers, singularity, and multicollinearity. Analyses were carried out to examine the location, shape, and spread of univariate distributions. Using the transformation utility, new variables were created as sums or products of existing variables, multiplicative composites and/or summative scores. EQS for Windows 5.1 was used to estimate correlated relationships item-to-scale and subscale-to-subscale. Coefficient alpha was executed on each scale, except the "Management Intensity

Scale" using EQS for Windows 5. Kuder-Richardson formula 20 was executed on the "Management Intensity Scale" using SPSS for Windows.

Symptom Intensity Scales

Originally, 16 items comprised the "Symptom Intensity Scale." Following recommendations of content experts and reconsideration of items after a repeated exploratory data analysis, this scale was divided into two separate scales: "Symptom Intensity G Scale" and the "Symptom Intensity B Scale." The division gave clarity to asthma symptoms occurring typical or average days during the last 30 days versus asthma symptoms occurring on atypical or bad days.

"Symptom Intensity G Scale" represented symptoms asthmatics had on average or good days during the month, whereas "Symptom Intensity B Scale" represented symptoms on bad days. "Symptom Intensity G Scale" consisted of item 44, 1-7. Item 45, 1-7 comprised the subscale Symptom Intensity B. Possible answers on the 4-point Likert Scale ranged from "none" to "all the time." As the scale was summative, the item-to-scale correlations were examined and all items falling below 0.3 or above 0.7 were eliminated (Nunnally, 1978). Items 4, 5, and 6 on both scales were excluded based on this criterion (Table 7 and Table 8).

Table 7

Symptom Intensity G Scale Item to Scale Correlation

	GWheeze	GSOB	GCough	GChTight	GFatigue	GIrritab
GWheeze	1.000					
GSOB	0.392	1.000				
GCough	0.251	0.387	1.000			
GChTight	0.533	0.581	0.487	1.000		
GFatigue	0.288	0.408	0.455	0.500	1.000	
GIrritab	0.300	0.302	0.411	0.580	0.595	1.000
GFear	0.299	0.292	0.271	0.465	0.340	0.629
Total SxGood	0.610	0.663	0.651	0.831	0.737	0.783

	GFear	SxGood
GFear	1.000	
Total SxGood	0.677	1.000

Table 8

Symptom Intensity B Scale Item to Scale Correlation

	BWheeze	BSOB	BCough	BChTight	BFatigue	BIrritab
BWheeze	1.000					
BSOB	0.681	1.000				
BCough	0.592	0.797	1.000			
BChTight	0.534	0.644	0.619	1.000		
BFatigue	0.453	0.631	0.648	0.655	1.000	
BIrritab	0.453	0.610	0.537	0.686	0.825	1.000
BFear	0.451	0.654	0.552	0.631	0.692	0.813
Total SxBad	0.697	0.659	0.615	0.824	0.859	0.864

	BFear	SxBad
BFear	1.000	
Total SxBad	0.641	1.000

Reliability. Internal consistency was determined using Cronbach's alpha coefficient of reliability. Alpha for the reformulated "Symptom Intensity G Scale" was 0.757. Reformulated item to scale correlations ranged from 0.610 to 0.677. Subscale Symptom Intensity B had an alpha coefficient of 0.868. Reformulated item to scale correlations ranged from 0.615 to 0.697. All were above 0.70 as recommended by Nunnally (1978) for newly developed instruments, each with 4 items.

Frequencies, mean, standard deviations, skew, and kurtosis. Information on the Symptom Intensity Scales is found in Table 9 and Table 10 on individual items in Appendix F. The 4-point Likert scales ranged from none to all the time. The highest obtainable score was 12. A mean of 6.48 was obtained on the "Symptom Intensity G Scale" and a mean of 8.72 on the "Symptom Intensity B Scale" with a range of 2 to 12 and 0 to 12, respectively. The higher the score on both scales, the worse the intensity of the symptoms. Patients demonstrated having higher scores or more intense symptoms on their bad or atypical days. Scores on the "Symptom Intensity G Scale" revealed a significant negative kurtosis. Kurtosis indicates whether a distribution has the right bell-shape curve. A curve with the right bell-shape results in a

value of zero; if the kurtosis value is negative, the curve is too flat to be normal (Munro & Page, 1993). Significant kurtosis indicated a platykurtic distribution of scores.

Table 9

Symptom Intensity G Scale Mean Standard Deviation, Skew, and Kurtosis

Possible	Mean	Median	Range	SD	Skew	Kurtosis
12	6.488	7.00	10.0	2.54	.271	-0.733**

** $z > 2.03$; $p \leq .01$.

Table 10

Symptom Intensity B Scale Mean Standard Deviation, Skew, and Kurtosis

Possible	Mean	Median	Range	SD	Skew	Kurtosis
12	8.724	10.0	12.0	3.09	-0.902	.020

Management Intensity Scale

The 16 items included in the "Management Intensity Scale" was item 38, 1-16. This scale contained factually

stated items addressed by respondents as "yes" or "no". Item-to-scale correlations below 0.3 and above 0.7 (Nunnally, 1978) eliminated items 1, 3, 4, 5, 6, and 13. Items dealt with skills patient used to manage their asthma (Table 11).

Reliability. Kuder Richardson formula 20 was used to determine reliability. Alpha for the reformulated "Management Intensity Scale" with this sample was 0.724. This scale was above 0.70 as recommended by Nunnally (1978) for newly developed instruments. Reformulated item to scale correlations ranged from 0.386 to 0.599 for the 10-item scale.

Frequencies, mean, standard deviation, skew, and kurtosis. Details on the Management Intensity Scale are found in Table 12 and information on individual items is in Appendix F. Scores were based on a dichotomous scale. The highest obtainable score was 10 and the lowest 0. The mean for this sample was 6.40 with a range from 1.0 to 10.0. The higher the score the more management skills demonstrated by the asthmatic. Scores on the "Management Intensity Scale" revealed a significant negative kurtosis. Significant kurtosis indicated a platykurtic distribution of scores.

Table 11

Management Intensity Scale Item to Scale Correlation

	Mspac	Mpf	Mhot	Mmatpad	Mpilpad	Mcare
Mspac	1.000					
Mpf	0.259	1.000				
Mhot	0.178	0.111	1.000			
Mmatpad	0.015	0.399	0.244	1.000		
Mpilpad	0.047	0.298	0.210	0.616	1.000	
Mcare	-0.076	0.017	-0.083	-0.013	-0.089	1.000
Mplan	0.020	0.154	0.056	-0.004	0.293	-0.091
Mrecog	-0.041	0.031	0.228	0.042	0.146	0.063
Msx	0.266	0.330	-0.009	0.129	0.211	0.121
Mpo	0.121	0.156	0.132	0.131	0.084	0.177
Mcalm	-0.111	0.090	-0.032	0.088	0.119	0.144
MED	0.068	0.150	-0.018	0.127	-0.029	-0.018
Mmd	0.094	0.141	0.217	0.172	0.222	0.004
Mmeds	-0.018	0.173	0.220	-0.048	0.011	0.175
Mmedex	0.135	0.297	0.099	0.196	0.273	0.003
Msigns	-0.035	0.227	0.121	0.110	0.187	0.104
Total Manage	0.288	0.516	0.196	0.226	0.298	0.275

	Mplan	Mrecog	Msx	Mpo	Mcalm	MED
Mplan	1.000					
Mrecog	0.321	1.000				
Msx	0.263	0.128	1.000			
Mpo	0.292	0.315	0.337	1.000		
Mcalm	0.253	0.247	0.216	0.353	1.000	
MED	0.017	0.152	0.157	0.121	0.069	1.000
Mmd	0.256	0.073	-0.015	0.022	0.027	0.092
Mmeds	0.286	0.135	0.203	0.178	0.096	0.124
Mmedex	0.284	0.275	0.222	0.232	0.169	0.192
Msigns	0.281	0.244	0.250	0.314	0.116	0.184
Total Manage	0.558	0.489	0.581	0.599	0.451	0.386

	Mmd	Mmeds	Mmedex	Msigns	Manage
Mmd	1.000				
Mmeds	-0.147	1.000			
Mmedex	0.129	0.181	1.000		
Msigns	0.051	0.269	0.250	1.000	
Total Manage	0.271	0.437	0.574	0.544	1.000

Table 12

Management Intensity Scale Mean Standard Deviation, Skew and Kurtosis

Possible	Mean	Median	Range	SD	Skew	Kurtosis
10	6.40	7.00	9.0	2.49	-0.395	-0.633**

** $z > 1.85$; $p \leq .01$.

Functional Status Scale

The "Functional Status Scale" asked respondents to evaluate their limitations on activities during the day. This summative subscale was formed from 10 items, 74 through 83. The responses formulated a 3-point format with 2 points for a response of yes, a lot, 1 point for yes, a little, and zero points for not at all. Nunnally (1978) supports the concept that items with correlations above 0.7 suggest redundancy. Examination of items on this scale with correlations above 0.7 confirmed this concept, therefore items 76, 78, 80, and 81 were also eliminated (Table 13).

Table 13

Functional Status Scale Item to Scale Correlation

	Run	Moving	Lifting	Clim2	Clim1	Bending
Run	1.000					
Moving	0.434	1.000				
Lifting	0.459	0.520	1.000			
Clim2	0.589	0.500	0.557	1.000		
Clim1	0.522	0.552	0.568	0.628	1.000	
Bending	0.314	0.372	0.529	0.325	0.550	1.000
Walk3	0.569	0.543	0.458	0.531	0.611	0.442
Walk2	0.525	0.459	0.398	0.546	0.607	0.343
Walk1	0.277	0.435	0.458	0.344	0.501	0.413
Dressing	0.028	0.208	0.400	0.022	0.245	0.564
Total Function	0.647	0.698	0.754	0.697	0.818	0.697

	Walk3	Walk2	Walk1	Dressing	Function
Walk3	1.000				
Walk2	0.736	1.000			
Walk1	0.529	0.657	1.000		
Dressing	0.152	0.150	0.444	1.000	
Total Function	0.781	0.763	0.629	0.476	1.000

Reliability. Cronbach's alpha coefficient was used to determine reliability. Alpha for the Functional Status Scale with this sample was 0.765. This scale was above the 0.70 as recommended by Nunnally (1978) for newly developed instruments. Reformulated item to scale correlations ranged from 0.476 to 0.697 for the 6-item scale.

Frequencies, mean standard deviation, skew, and kurtosis. Information on the Functional Status Scale is found in Table 14 and on individual items in Appendix F. The 3-point Likert Scale ranged from yes, a lot to not at all. The highest obtainable score was 18 with a mean off 6.95 and a range of 1 to 12. A higher score described a decrease in performing functions of everyday living. Patients agreed to having a decrease in functional status with most having difficulty climbing stairs. Scores on the "Functional Status Scale" revealed a significant negative kurtosis. Significant kurtosis indicated a platykurtic distribution of scores.

Table 14

Functional Status Scale Mean Standard Deviation, Skew, and Kurtosis

Possible	Mean	Median	Range	SD	Skew	Kurtosis
18	6.98	7.00	11.0	3.15	-0.05	-1.080**

** $z > 3.14$; $p \leq .01$.

Environmental-Impact Scale

The Environmental-Impact Scale was formulated using multiplicative composite and weighted scores. This subscale was formed from item 36, A-O and item 37, A-J (Table 15). Items dealt with an asthmatic's sensitivities and exposures to aeroallergens and environmental allergens. Respondents answered "yes" or "no" to items addressing sensitivities and exposures. Changes in weather and pollution (36 a,e) were weighted to a multiplicative value of 2 times the response. Two was an arbitrary weight given due to the geographical effect and frequency of weather changes in Texas and recommendations of content experts. Grass, tree, and weed pollen were combined as one composite subscore. Exposure and sensitivities to dogs and cats were multiplicative with a weight of one for either animal living outside and two times the value for either animal living inside the house. All other items were given a value of one. After items transformed were summed to formulate scale.

Table 15

Environmental-Impact Scale Item to Scale Correlation

	Weather	GTW	Pollutio	Indog	Outdog	Incat
Weather	1.000					
GTW	0.272	1.000				
Pollutio	0.217	0.520	1.000			
Indog	0.087	0.225	0.204	1.000		
Outdog	-0.063	0.164	0.101	0.426	1.000	
Incat	0.051	0.117	-0.013	0.208	-0.040	1.000
Outcat	0.039	-0.067	-0.078	-0.033	-0.031	0.244
Roach	0.171	0.326	0.252	0.416	0.269	0.298
Smoke	0.081	-0.045	0.156	-0.010	-0.095	0.001
Colds	0.233	0.234	0.245	0.077	-0.075	-0.022
Dust	-0.018	0.190	0.217	-0.004	0.024	0.068
Molds	0.123	0.358	0.226	0.128	0.029	0.129
Total E-IScale	0.442	0.742	0.708	0.435	0.226	0.233

	Outcat	Roach	Smoke	Colds	Dust	Molds
Outcat	1.000					
Roach	0.229	1.000				
Smoke	-0.047	-0.220	1.000			
Colds	-0.037	-0.101	-0.028	-0.028		
Dust	0.067	-0.020	0.122	0.039	1.000	
Molds	-0.047	0.008	0.011	0.005	0.417	1.000
Total E-IScale	0.037	0.450	0.191	0.399	0.476	0.452

Reliability. Cronbach's alpha coefficient was used to determine reliability. Alpha for the reformulated Environmental-Impact Scale with this sample was 0.744. This scale was above 0.70 as recommended by Nunnally (1978) for newly developed instruments. Reformulated item

to scale correlations ranged from 0.233 to 0.742 for the 9-item scale. Items, such as sensitivity and exposure to pollens, pollution, and cat were not deleted although they fell either above or below the recommended 0.30 or 0.70 qualifier. Without these items there would be theoretical incongruencies within the subscale. The low and high scores may be the result of the current sample and in future studies will be reanalyzed.

Frequencies, mean, standard deviations, skew, and kurtosis. Details on the Environmental-Impact Scale are found in Table 16 and information on individual items is in Appendix F. The highest obtainable score was 19 and the lowest 0. The mean for this sample was 8.17. The higher the score, the more the impact of aeroallergens and environmental allergens on the asthmatic. Patients were found to have more aeroallergens than environmental allergens. Scores did not reveal significant skewness or kurtosis.

Table 16

Environmental-Impact Scale Mean Standard Deviation, Skew and Kurtosis

Possible	Mean	Median	Range	SD	Skew	Kurtosis
19	8.17	8.0	19.0	3.62	-0.079	-0.057

Somatic Vulnerability Scales

Originally 25 items comprised the "Somatic Vulnerability Scale". Following reconsideration of items after a repeated exploratory factor analysis of scale items the scale was divided into two separate scales. The two subscales were the "Somatic Vulnerability A Scale" and the "Somatic Vulnerability B Scale." "Somatic Vulnerability A Scale" represented the asthmatic's perception of their management skills. These negatively worded items were recoded so the higher the score the more positive the perception toward management skills. "Somatic Vulnerability B Scale" represented the asthmatic's predisposition to illness based on the individual's social support, locus of control, and coping. "Somatic Vulnerability A Scale" consisted of item 51, 58, 61, 62, 65, 66, 67, 71 and 73. Item 49, 50, 52, 53, 54, 55, 56, 57, 59, 60, 63, 64, 68, 69, 70, and 72 comprised

the subscale Somatic Vulnerability B Scale (Table 17 and Table 18).

Table 17

Somatic Vulnerability A Scale Item to Scale Correlation

	Q51	Q58	Q61	Q62	Q65	Q66
Q51	1.000					
Q58	0.137	1.000				
Q61	-0.092	0.127	1.000			
Q62	0.056	0.077	0.323	1.000		
Q65	-0.147	0.031	0.242	0.333	1.000	
Q66	-0.018	0.196	-0.000	-0.009	0.140	1.000
Q67	-0.047	0.061	0.169	0.266	0.395	0.202
Q71	0.010	-0.040	-0.040	0.068	0.028	0.065
Q73	0.039	-0.080	-0.082	-0.082	0.008	0.073
Total SOMScA	0.263	0.449	0.393	0.530	0.512	0.470

	Q67	Q71	Q73	SOMScA
Q67	1.000			
Q71	0.116	1.000		
Q73	0.131	0.028	1.000	
Total SOMScA	0.510	0.407	0.253	1.000

Table 18

Somatic Vulnerability B Scale Item to Scale Correlation

	Q49	Q50	Q52	Q53	Q54	Q55
Q49	1.000					
Q50	0.209	1.000				
Q52	0.073	0.284	1.000			
Q53	0.154	0.213	0.192	1.000		
Q54	0.135	0.169	0.072	0.090	1.000	
Q55	0.140	0.140	0.123	0.203	0.367	1.000
Q56	0.119	0.119	0.306	0.025	0.210	0.179
Q57	0.127	0.127	0.164	0.080	0.321	0.248
Q59	0.127	0.127	0.144	-0.008	0.399	0.348
Q60	0.138	0.081	-0.004	-0.027	0.460	0.314
Q63	0.233	0.213	0.206	0.047	0.170	0.257
Q64	0.197	0.166	0.065	0.061	0.485	0.324
Q68	0.360	0.313	0.208	0.123	0.310	0.307
Q69	-0.032	0.176	0.220	0.017	0.078	0.124
Q70	-0.026	0.214	0.170	0.139	0.049	0.163
Q72	0.224	0.027	0.118	0.129	0.133	-0.069
Total SOMScB	0.368	0.449	0.433	0.336	0.574	0.539

	Q56	Q57	Q59	Q60	Q63	Q64
Q56	1.000					
Q57	0.098	1.000				
Q59	0.141	0.243	1.000			
Q60	-0.005	0.252	0.575	1.000		
Q63	0.145	0.506	0.255	0.269	1.000	
Q64	0.035	0.300	0.522	0.610	0.434	1.000
Q68	0.149	0.273	0.321	0.270	0.445	0.371
Q69	0.127	0.289	0.246	0.061	0.195	0.041
Q70	0.087	0.116	0.179	0.092	0.089	0.102
Q72	-0.028	0.176	0.182	0.152	0.051	0.201
Total SOMScB	0.327	0.562	0.623	0.547	0.569	0.628

	Q68	Q69	Q70	Q72	SOMScB
Q68	1.000				
Q69	0.223	1.000			
Q70	0.236	0.445	1.000		
Q72	0.108	0.118	-0.030	1.000	
Total SOMscB	0.638	0.442	0.404	0.332	1.000

Reliability. Internal consistency was determined using Cronbach's alpha coefficient of reliability. Somatic Vulnerability A had an alpha coefficient of 0.524. Reformulated item to scale correlations ranged from 0.393 to 0.530 for this 7-item scale. Somatic Vulnerability B had an alpha coefficient of 0.785. No items were deleted from the original 16 item scale, the item to scale correlations ranged from 0.332 to 0.638. The Somatic Vulnerability B Scale was above 0.70 as recommended by Nunnally (1978) for newly developed instruments.

Frequencies, mean, standard deviations, skew, and kurtosis. Information on the Somatic Vulnerability Scales is found in Table 19 and Table 20 and on individual items in Appendix F. The 3-point Likert scales ranged from always true to not true. The highest obtainable score was 14 on the "Somatic Vulnerability A Scale" and 32 on the "Somatic Vulnerability B Scale" with a mean of 4.79 and 12.02 respectively. Scores on the Somatic Vulnerability B Scale revealed a significant negative kurtosis. Significant kurtosis indicated a platykurtic distribution of scores. The 3-point Likert scales ranged from always true to not true. The highest obtainable score was 14 on the "Somatic Vulnerability A Scale" and 32 on the "Somatic Vulnerability B Scale" with a mean of 4.79 and 12.02,

respectively. Many patients revealed a low score reflecting a low level of social support and coping, but perceived they were managing their asthma adequately. Scores on the "Somatic Vulnerability B Scale" revealed a significant negative kurtosis. Significant kurtosis indicated a platykurtic distribution of scores.

Table 19

Somatic Vulnerability A Scale Mean Standard Deviation, Skew, and Kurtosis

Possible	Mean	Median	Range	SD	Skew	Kurtosis
14	4.798	5.0	12.0	2.43	0.109	-0.129

Table 20

Somatic Vulnerability B Scale Mean Standard Deviation, Skew, and Kurtosis

Possible	Mean	Median	Range	SD	Skew	Kurtosis
32	12.02	12.0	19.0	4.38	0.157	-0.380**

** $z > 1.1$; $p \leq .01$.

Medication Management Intensity Scale

The "Medication Management Intensity Scale" was formulated to identify which medications asthmatics took

to treat their illness. This included what they took, how much and when. This subscale was formed from item 48 (Table 21).

Table 21

Medication Management Intensity Scale Item to Scale Correlation

	Rbeta	Rneb	Rtheo	Rpred30	RIV30	Dbeta
Rbeta	1.000					
Rneb	-0.034	1.000				
Rtheo	-0.196	-0,022	1.000			
Rpred30	0.028	0.218	-0.171	1.000		
RIV30	-0.136	0.136	0.578	-0.124	1.000	
Dbeta	-0.105	-0.034	0.208	-0.018	-0.039	1.000
Dsere	-0.006	-0.045	0.045	0.262	-0.090	0.173
DTheo	0.004	0.095	0.315	0.159	-0.080	0.210
DsterMDI	0.226	0.216	-0.125	0.353	-0.076	-0.018
Atrovent	0.006	-0.115	-0.065	0.205	-0.047	0.121
Nedcromi	-0.070	0.141	-0.037	0.115	-0.027	-0.052
Chrom	-0.119	-0.007	0.297	0.089	-0.025	-0.048
ChroSter	-0.018	0.403	0.0225	0.465	0.090	0.139
Total Med Score	0.453	0.402	0.087	0.380	-0.044	0.232

	Dsere	DTheo	DSter MDI	Atrovent	Nedcromi	Chrom
Dsere	1.000					
Dtheo	0.296	1.000				
DsterMDI	0.454	0.141	1.000			
Atrovent	0.331	0.145	0.201	1.000		
Nedcromi	-0.120	-0.107	-0.120	-0.016	1.000	
Chrom	-0.023	0.280	-0.052	-0.058	0.286	1.000
ChroSter	0.359	0.373	0.250	0.060	0.152	0.180
Total Med Score	0.615	0.509	0.703	0.319	-0.030	0.062

Reliability. Cronbach's alpha coefficient was used to determine reliability. Alpha for the reformulated "Medication Management Intensity Scale" with this sample was 0.637. This scale was lower than a 0.70 as recommended by Nunnally (1978) for newly developed instruments. Reformulated item to scale correlations ranged from 0.319 to 0.703. One item, daily use of inhaled steroids, greater than the recommended 0.70 remained based on theoretical considerations for the 8-item scale.

Frequencies, mean, standard deviations, skew, and kurtosis. Details on the "Medication Management Intensity Scale" are found in Table 22 and information on individual items is in Appendix F. The highest obtainable score was 21 and the lowest 0. The mean for this sample was 8.35. Scores did not reveal significant skewness or kurtosis.

Table 22

Medication Management Intensity Scale Mean Standard Deviation, Skew, and Kurtosis

Possible	Mean	Median	Range	SD	Skew	Kurtosis
21	8.35	8.0	21.0	4.63	0.486	0.060

In summary, reliability for each instrument was determined using Cronbach's coefficient alpha or KR-20. Squared multiple correlations also served as a reliability estimate. The Symptom Intensity G and B Scales, Functional Status Scale, Somatic Vulnerability B Scale and the Environmental-Impact Scale met Nunnally's (1978) criterion for correlation alpha of 0.70 or higher for new instruments (α = 0.757, 0.868, 0.765, 0.785, and 0.744, respectively). Also, using the K-R 20 for dichotomous measures, the Management Intensity Scale met Nunnally's (1978) criterion for correlation alpha of 0.70 or higher (α = 0.724). Correlations alpha for the Somatic Vulnerability A Scale (α = 0.524) and Medication Management Intensity Scale (α = 0.637) fell below the recommended alpha level. The researcher chose not to eliminate any scale for the possibility of theoretical incongruencies and newness of the instruments. Table 23 relates all alpha coefficients of reliability and squared multiple correlations of scales.

Table 23

Alpha Correlation Coefficients for All Scales and Squared Multiple Correlations

Subscale	No. Items	Alpha	Multiple R2 Model 1	Model2
Symptom Intensity G Scale	4	0.757	0.57	0.59
Symptom Intensity B Scale	4	0.868	0.64	0.66
Management Intensity Scale	10	0.724	0.26	1.00 Fixed
Functional Status Scale	6	0.765	0.25	0.36
Environmental-Impact Scale	9	0.744	0.53	0.09
Somatic Vulnerability A Scale	7	0.524	0.14	0.71
Somatic Vulnerability B Scale	16	0.785	0.26	0.50
Medication Management Intensity Scale	8	0.673	0.14	0.16

Confirmatory Factor Analysis

In this section, confirmatory factor analysis (CFA) will be discussed regarding the validity of the eight newly developed scales. A CFA, to analyze measurement models, was applied to two models (Figure 3 and Figure 4).

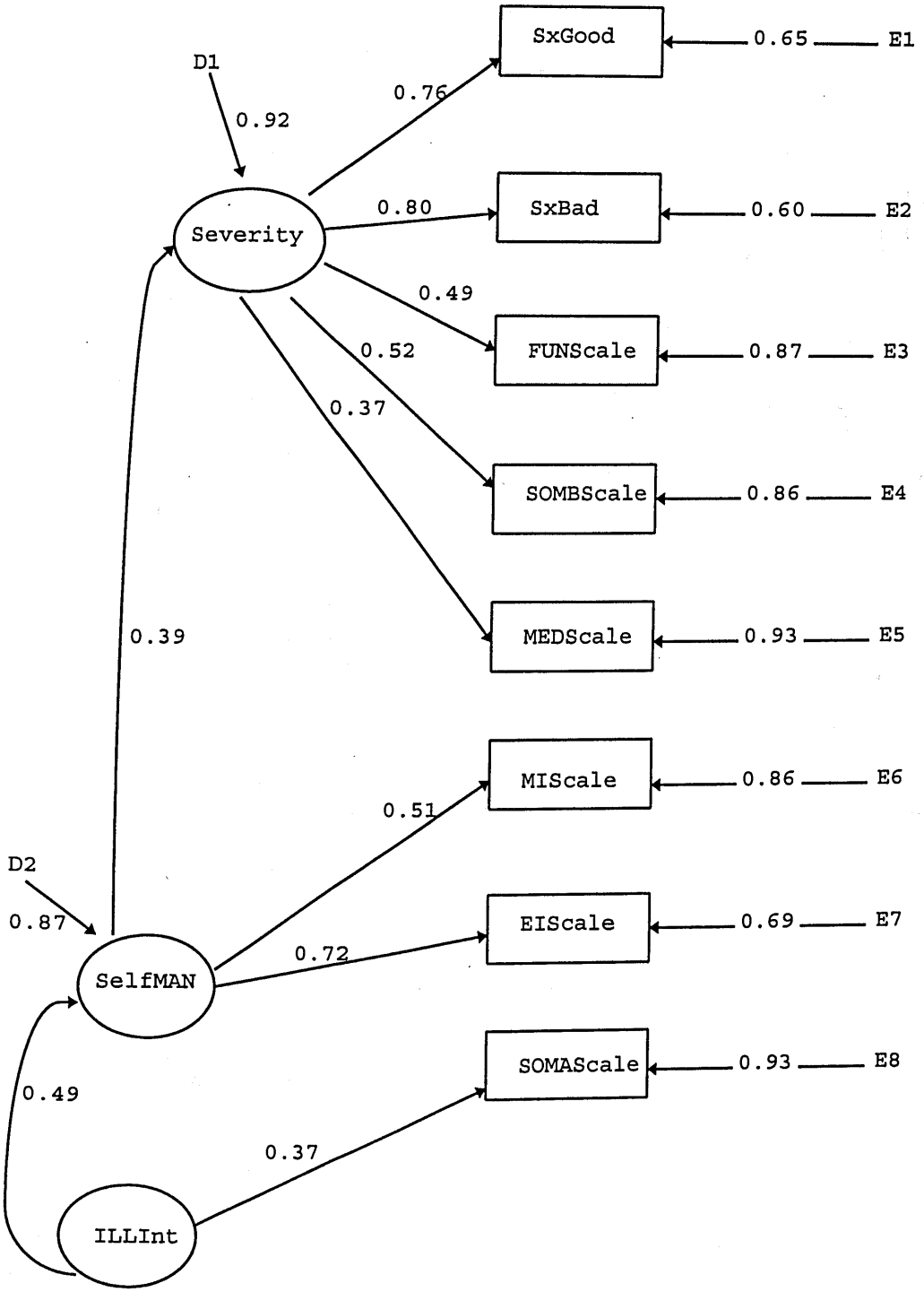

Figure 3. Model 1 (M1).

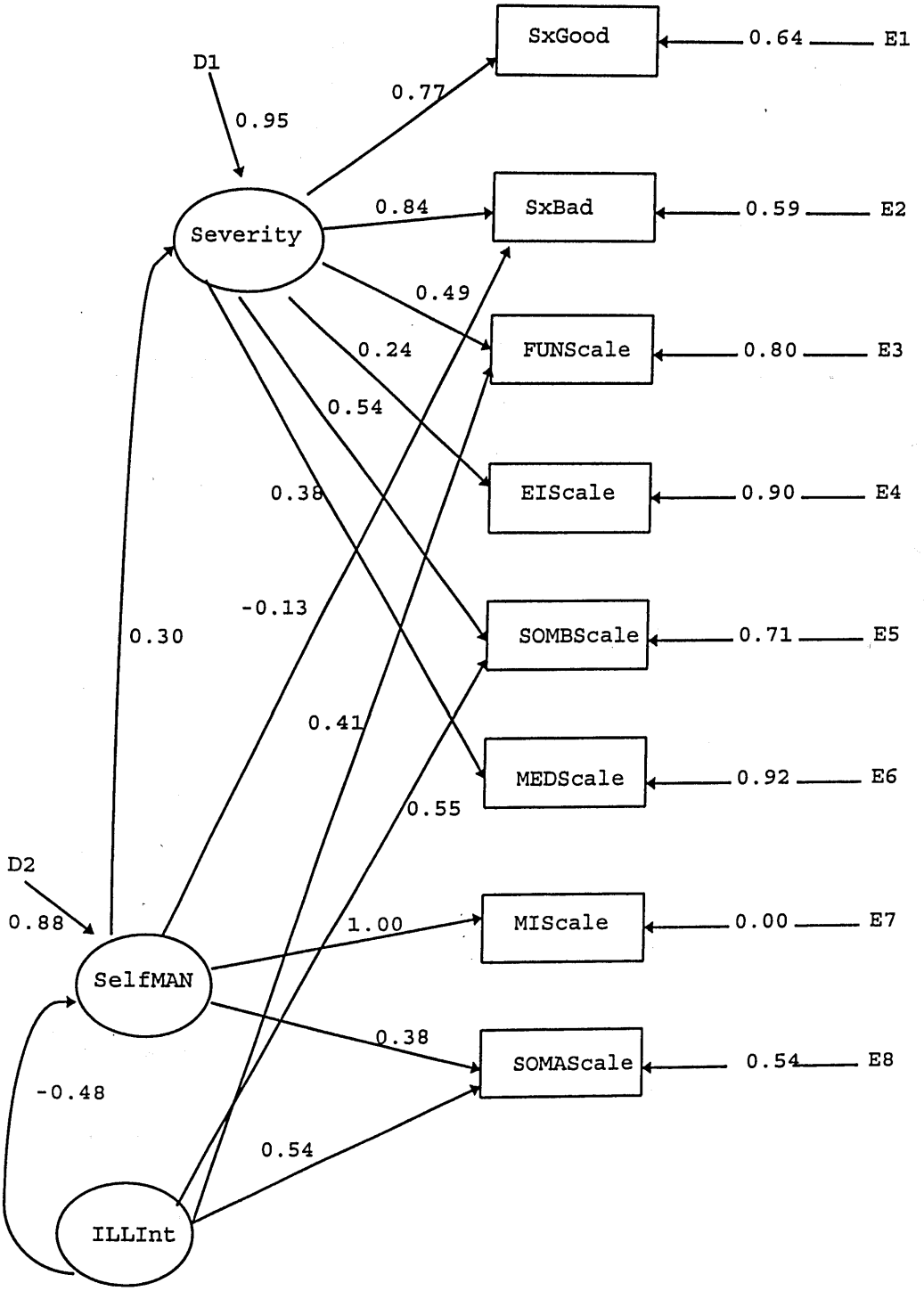

Figure 4. Model 2 (M2).

The primary objective of CFA concerns testing the researcher's hypothesis about how a domain of variables are structured. By combining factors of factor analysis and multiple regression, CFA allows the estimation of relationships among latent (unobserved) variables and one or more manifested (observed) indicators and permits for estimation of correlated residuals (Diamantopoulos, 1994; Lavee, 1988; Mason-Hawkes & Holm, 1989).

The assumption of CFA is that the parameters are not just descriptive measures of association, but rather reveal an invariant causal relation. Bollen (1989) states CFA shows whether the causal assumptions embedded in a model match the sample data. Diamantopoulos (1994) states CFA is different from exploratory in that confirmatory seeks to determine the extent to which the postulated structure is actually consistent with the empirical data at hand. Lavee (1988) confirms that the "fit" is of the models to the data rather to models derived from an exploratory analytical techniques using the same data. Furthermore, using a confirmatory approach, the measurement model defines the latent variables *a priori* in terms of their specified measured indicators describing how each of the latent variables is operationalized using the observable measures. However, an exception to this

rule is made when the study is measurement properties of an instrument where the measurement model can be determined *post priori* (Raykov & Widamon, 1995).

CFA was applied to the three-factor models, Model 1 (M1) and Model 2 (M2). M1 resulted from a factor analysis of subscales. Model 2 (M2) was a respecified model following analysis of Lagrange Multiplier Test and Wald Test. The Lagrange Multiplier Test (LM) is a test designed to evaluate the statistical necessity of model restrictions (Bentler & Wu, 1995). Restrictions evaluated are whether a parameter fixed at a given value is appropriate or might be better left free to estimate or if an equality restriction is appropriate for the data. The Wald Test (W) is a test on the free parameters to determine if the free parameters could be zero in the population (Bentler & Wu, 1995). Discussion of results of the confirmatory factor analysis will include (a) specification of the models, (b) identification and estimation of the models, and (c) testing fit (Bollen & Long, 1993).

Specification

Model specification refers to the initial model(s) that the researcher formulates prior to estimation (Jöreskog & Sorbom, 1993). Based on the subscale factor

analysis in Table 24, Model 1 was specified as a three factor model and tested using EQS 5.1. The three factors were renamed Illness Intensity, Self- Management and Severity (Figure 3). The factor to factor correlation is presented in Table 25.

Table 24

Factor Analysis of Subscales

INITIAL FACTOR LOADINGS (PRINCIPAL COMPONENTS)

	FACTOR 1	FACTOR 2	FACTOR 3
SxGood	0.7646	-0.0451	-0.2841
SxBad	0.7867	0.0426	-02379
MIScale	0.2807	-0.7907	0.2414
FUNScale	0.6513	0.3478	0.0848
EIScale	0.4349	-0.5801	0.1041
SOMBScale	0.6254	0.4905	0.1135
SOMAScale	0.2786	0.1481	0.8887
MedScale	0.5069	-0.1959	-0.1626
Eigenvalue	2.621	1.387	1.043
Percentage of Variance	33%	17%	13%
Total Variance	63%		

FACTOR LOADINGS (OBLIQUE SOLUTION)

	FACTOR 1	FACTOR 2	FACTOR 3
SxGood	0.6732	-0.0342	-0.1873
SxBad	0.6926	0.0323	-0.1568
MIScale	0.2471	-0.5996	0.1591
FUNScale	0.5734	0.2637	0.0559
EIScale	0.3829	-0.4398	0.0686
SOMBScale	0.5506	0.3719	0.0748
SOMAScale	0.2453	0.1123	0.5857
MedScale	0.4463	-0.1486	-0.1072

FACTOR LOADINGS (ORTHOGONAL SOLUTION)

	FACTOR 1	FACTOR 2	FACTOR 3
SxGood	0.6646	0.2185	0.0044
SxBad	0.6884	0.1683	0.0557
MIScale	0.0172	0.6654	0.0540
FUNScale	0.5657	-0.0488	0.2812
EIScale	0.2115	0.5454	0.0510
SOMBScale	0.5659	-0.1535	0.3215
SOMAScale	0.0481	0.0770	0.6385
MedScale	0.4030	0.2648	-0.0153

Table 25

Factor Correlation Matrix

	Factor 1 Severity	Factor 2 Self-Management	Factor 3 Illness Intensity
Factor 1 Severity	1.00		
Factor 2 Self-Management	-0.235	1.00	
Factor 3 Illness Intensity	-0.207	-0.094	1.00

In Figure 4, the Asthma Model was respecified (Table 26). The respecification was based on the Lagrange Multiplier (LM) Test and the Wald (W) Test. Both tests evaluated and modified the model by freeing or fixing the parameters. The LM Test pinpointed misfit in the misspecified model and provided parameter change statistics to identify how the model could be improved by relaxing constraints. The W Test tested multivariately for redundant structural paths in the models (Bentler, 1989, 1992a; Byrne, 1994).

Table 26

Specification and Respecification Parameters in Confirmatory Factor Analysis of M1 and M2

	Model 1			Model 2		
	F1	F2	F3	F1	F2	F3
SxGood	*			*		
SxBad	*			*	*	
MIScale		*			*	
FunScale	*			*		*
EIScale		*		*	*	
SOMBScal	*			*		*
SOMAScal			*		*	*
MedScale	*			*		

Factor 1 (F1) = Severity
Factor 2 (F2) = Self-Management
Factor 3 (F3) = Illness Intensity

Identification

Determining the adequacy of the data to be used to estimate the causal parameters in the models is referred to as identification. Identification concerns the correspondence between the information to be estimated, the free parameters, and the information from which it is to be estimated, the observed variances and covariances (Hoyle, 1995). Identification is concerned with whether a

single unique value for each free parameter can be obtained from the observed data. If a model is not identified, it is impossible to uniquely determine the parameters even if the values for each observed variable are known for the entire population. Identification can be determined using the T-rule, where the number of observed variables p is equal to, less than, or greater than the parameters to be estimated.

Following the T-rule, there are 8 observable variables in M1 and M2, $8(8+1)/2 = 36$ data points. Accordingly, there are 8 regression coefficients, 2 factor covariances, 8 error variances, and 3 factor variances. Thus, with 36 data points and 21 parameters to be estimated there is an overidentified model with 15 degrees of freedom in M1. In M2 there are 11 regression coefficients, 2 factor covariances, 8 error variances, and 3 factor variances. Thus, with 36 data points and 24 parameters to be estimated there is an overidentified model with 12 degrees of freedom (Table 27).

Table 27

Model Identification

	Data Points p (p+1)/2	Parameters	Degrees of Freedom	Identification
Model 1 (M1)	36	21	15	Over-identified
Model 2 (M2)	36	24	12	Over-identified

Overidentification of models is a necessary but not sufficient condition for identification (Byrne, 1995).

Estimation

Estimation assumes the model is identified. While justification for estimating the parameters is contingent upon the identification of the model, identification and estimation are distinct issues. Identification as previously discussed is concerned with whether or not the parameters of the model are uniquely determined, whereas estimation involves using sample data to make estimates of population parameters. In the confirmatory factor model, this involves using the sample matrix of covariances to estimate the parameters. These estimates result in predictions of the population variances and covariances of the observed variables (Long, 1983).

Maximum Likelihood Solution (MLS) was the method of statistical estimation used which sought to identify the

population parameters with a maximum likelihood of generating the observed sample distribution (Long, 1985). Estimating several models permitted exploration of other plausible structures. The comparison of M1 and M2 allowed determination of a model with the best fit rather than attempting to assess a single model's fit in the absolute sense (Bollen, 1993).

Goodness-of-Fit-Statistics

Table 28 summarizes the indices of fit of the Asthma Model. A model is said to fit the observed data to the extent that the population matrix it implies is equivalent to the observed matrix. In structural equation modeling the chi-square value is considered a test of goodness of fit of the model to the data. The chi-square is sensitive to sample size and estimates (Jöreskog & Sorbom, 1989).

Two models were analyzed. Models 1 and 2 are competing or nested models. Nested models are hierarchically related to one another in the sense that one is a subset of another; for example, particular parameters are freely estimated in one model but fixed to zero or one in a second model (Bentler & Chou, 1987; Byrne, 1994; Long, 1983). By adding an additional three paths to Model 1 and, maintaining theoretical congruency, Model 2 had better model fit.

Table 28

Summary of Goodness-of-Fit Statistics for the Asthma Measurement Models M1 and M2

	Model 1	Model 2
Degrees of Freedom	15	12
χ^2	69.013 $p < .001$	19.899 $p = .069$
NFI	0.784	0.938
CFI	0.815	0.973
AGFI	0.818	0.933
GFI	0.924	0.978
RMSEA	0.130	0.060
RMR	0.080	0.036
Standardized Residuals	-0.213 to 0.19	0.130 to 0.010

The desired outcome is a nonsignificant chi-square value to indicate no difference between the proposed model and a model generated from the data by the EQS program representing the population (Bollen, 1989; Jöreskog and Sorbom, 1989). In comparing M1 and M2 there is a decrease in the overall χ^2 value (χ^2 = 69.013, df 15) for Model 1 in comparison to Model 2 (χ^2 = 19.899, df 12). The decrease in χ^2 from Model 1 to Model 2 represents a highly

significant improvement in the goodness-of-fit. Consistent with statistical assessment, the CFI of 0.815 in M1 to 0.973 in M2 also reflects a substantial improvement in model fit.

Normalized Fit Index (NFI) was computed by comparing the chi square for the model to the chi-square for a null model generated by EQS. It is not affected by sample size or number of degrees of freedom. Addressing evidence that the NFI has a tendency to underestimate fit in small samples the Comparative Fit Index (CFI) was also examined. Values for both NFI and CFI range from zero to 1.00 and are derived from the comparison of a hypothesized model with the null model. Each provides a measure of complete covariation in the data, a value of greater than 0.90 indicating an acceptable fit to the data (Bentler, 1993). The NFI for the Asthma models, M1 and M2, was 0.784 and 0.938, respectively. The CFI of Model 1 was 0.815 and of Model 2, 0.973.

Unlike chi-square, the goodness-of-fit index (GFI) is not affected by sample size and is robust against departure from normality (Lavee, 1988). It is an indicator of the relative amount of variances and covariances jointly accounted by the model and shows how closely the proposed model comes to perfectly reproducing

the observed covariance matrix (Diamantopoulos, 1994; Jöreskog & Sorbom, 1982). A GFI above 0.90 indicates a good fit of the model to the data. The GFIs for the models were M1(0.924) and M2(0.978).

Adjusted goodness-of-fit index (AGFI) adjusts the GFI for the degrees of freedom (Bollen, 1989; Lavee, 1988). Small differences in the GFI and AGFI should be reflected, with the AGFI values ranging between 0.000 and 1.00. The closer to unity, the better the model fit (Diamantopoulos, 1994). An acceptable AGFI is one above 0.80 (Brooke et al., 1988; Lavee, 1988). AGFIs for the Asthma Models were M1 (0.818) and M2 (0.933). This represented a difference of 0.11 and 0.05 from the GFI.

Other fit indices include the root mean square error of approximation (RMSEA) and the root mean square residual (RMR). Following the guidelines of Browne and Cudeck (1993), the recommended point estimate of RMSEA is below 0.05. The RMSEA was above the recommended value of 0.05 in M1 (0.13) and M2 (0.06), it was concluded that the degree of approximation in these models and this sample was too large, but not significant in M2.

Root-mean-square-residual (RMR) is useful when comparing different models for the same data (Farmer et al., 1989; Jöreskog & Sorbom, 1989). The model with the

least RMR would be considered the best. The closer to zero the RMR, the better the fit with values less than 0.10 being desirable (Diamantopoulos, 1994; Lavee, 1988). Model 2 had an RMR of 0.036 while Model 1 was 0.080.

Standardized Residuals

Standardized residuals provide an approximate correlation for sample size and for scaling differences. Residuals should be small and evenly distributed among the variables if the model represents the data well. "The largest values indicate the most poorly fit elements" (Bollen, 1989, pp. 258-259). A value greater than 2.0 suggests serious specification error (Yarcheski & Mahon, 1989). Residuals were small in Model 1 and Model 2. The range for Model 1 was -0.213 to 0.190 and 0.130 to 0.010 for Model 2.

Hypotheses Tests

The Major Study Hypotheses

The primary objective of this research was to test the validity and reliability of the measurement model. Reliability and validity are evaluated differently in structural equation modeling than in other multivariate analysis. In SEM, the latent variables exert direct systematic effects on the measured variables; other

sources of variance are attributable to error. In multiple indicator models such as the Asthma Model, the measured variables can correlate or "load" onto more than one latent construct or correlate among themselves. In this situation the squared multiple correlation coefficient (R^2) for each indicator represents the reliability estimate for that indicator (Bollen, 1993).

Hypothesis 1

The estimated degrees of internal consistency of items indicating the character of asthma and its concepts are greater than an alpha coefficient of 0.70 in the sample.

Item-to-scale correlations for all items were used to eliminate items with correlation to scale below 0.3 and at or above 0.7 (Nunnally, 1978). Three items were dropped from the Symptom Intensity G and B Scales leaving 4 items. Management Intensity Scale deleted 6 items leaving 10 items. Four items were removed from the Functional Status Scale with 6 items remaining. The Environmental-Impact Scale had 3 items deleted leaving 10 items. All items on the Somatic Vulnerability B Scale met criteria, therefore 16 items remained. However, the Somatic A Scale had 2 items deleted leaving 7 items. Finally, the Medication

Management Intensity Scale dropped 5 items leaving 8 items.

Six of the eight scales demonstrated acceptable reliability: (a) the "Symptom Intensity G Scale" (α = 0.757; multiple $\underline{R^2}$ = 0.57 and 0.59); (b) the "Symptom Intensity B Scale" (α = 0.868; multiple $\underline{R^2}$ = 0.64 and 0.66); (c) the "Management Intensity Scale" (α = 0.724; multiple $\underline{R^2}$ = 0.26); (d) the "Functional Status Scale" (α = 0.765; multiple $\underline{R^2}$ = 0.25 and 0.36); (e) the "Environmental-Impact Scale" (α = 0.744; multiple $\underline{R^2}$ = 0.53 and 0.09), and (f) the "Somatic Vulnerability B Scale" (α = 0.785; multiple $\underline{R^2}$ = 0.26 and 0.50). The "Somatic Vulnerability A Scale" lacked sufficient internal consistency to be considered adequate (α = 0.524; multiple $\underline{R^2}$ 0.14 and 0.71) as did the "Medication Management Intensity Scale" (α = 0.673; $\underline{R^2}$ 0.14 and 0.16).

Hypothesis 2

The theoretical model of asthma demonstrated a statistical fit to the observed data. Validity refers to the magnitude of the direct structural relation between a measure and its latent Construct (Bollen, 1993). If the model fits the data well, the resulting path coefficient maybe interpreted as a factor loading or statistical estimate of the validity of the measure. Confirmatory

factor analysis using maximum likelihood (ML) goodness-of-fit determined the validity and fit of the models to the data.

Summary of Findings

Demographic data were collected on the sample. Mean age was 42 years, most (82%) were female, belonging to a minority group (82%), and having incomes below $29,999 (87%). They received treatment for asthma in the Emergency Department (80%) and had prescriptions filled in the hospital pharmacy (97%). The average number of medications taken by a subject for asthma was 4. A mean of 8 was rated by subjects on a 15-point visual analog scale, asking subjects how they felt about their quality of life.

Exploratory factor analysis yielded no extractable, theoretically-logical factors on any of the instruments, however, a repeated exploratory data analysis extracted eight subscales. Items with item to scale correlations below 0.3 and above 0.7 were excluded from the analysis. Remaining items comprised the reformulated scales for analysis.

The reformulated "Symptom Intensity G Scale" (4 items) and the "Symptom Intensity B Scale" (4 items) used a 4-point Likert Scale from none to all the time. The dichotomous "Management Intensity Scale" has 10 items. The Environmental-Impact Scale" (9 items) is a summative composite score. The "Functional Status Scale" (6 items) used a 3-point Likert Scale from yes, a lot, to not at all. The "Somatic Vulnerability B Scale" (16 items) and the "Somatic Vulnerability A Scale" (7 items) is a 3-point Likert Scale from always true to not true. The 8 items of the "Medication Management Scale" asked patients what medications they took, how often, and how much.

All of the measures except the "Somatic Vulnerability A Scale" (α = 0.524) and the "Medication Management Scale" (α = 0.637) had alpha coefficients for internal consistency of 0.70 or above. Both scales with an internal consistency less than 0.70 remained in further analysis to maintain theoretical congruencies.

Frequencies, mean, standard deviation, skew, and kurtosis were estimated on each subscale and all items. Skewness was not obtained on any of the scales. However, significant negative kurtosis was obtained on the "Symptom Intensity G Scale", "Management Intensity Scale," "Functional Status Scale", and "Somatic Vulnerability B Scale.

A subscale factor analysis yielded three theoretically-logical factors on the instrument. These factors were identified as Illness Intensity, Self-Management, and Severity. A confirmatory factor analysis identified two nested three-factor models. Goodness-of-fit statistics indicated an excellent fit of M2 to the data.

CHAPTER V

SUMMARY OF THE STUDY

The problem of the study focused measuring on the attributes which represent the character of asthma in adults. The purpose of the methodological study was to develop, refine, and estimate the psychometric properties of the researcher-developed Asthma Outcome Index (AOI). The initial segment of the study involved identification of the attributes that represent asthma. Following the writing of items and the construction of the AOI, content validity was evaluated by experts with expertise in the area of asthma. The instrument was pilot tested and revised in the light of content expert evaluation, participant feedback, and data analysis. The instrument was rewritten in readiness for the psychometric study. Two hypotheses related to reliability and validity were proposed prior to collection of data. This chapter presents a summary of the study, a discussion of findings, conclusions and implications, and recommendations for further study.

Synopsis

This methodological study was designed for the purpose of producing a valid and reliable instrument to measure the character of asthma. A theoretical framework grew from a shared belief among asthma health care providers that severity of disease and patient management depended on successful measurement of multiple factors. The construction of the Asthma Outcome Index(AOI) was guided by the Asthma Model.

The model was developed by the researcher through the processes of concept analysis, synthesis and derivation (Walker & Avant, 1988), and theory construction (Blalock, 1969). The original concepts of the model included: Physiological Intensity, Somatic Vulnerability, Self-Management, Medication Management Intensity, Symptom Intensity, Functional Status and Well Being. On completion of the study the concepts of the model considered attributes critical to the character of asthma were: Severity, Self-Management, and Illness Intensity.

No data collection instruments were located to measure collectively the concepts. Therefore, the Asthma Outcome Index was developed including eight subscales the "Symptom Intensity G Scale," the "Symptom Intensity B Scale,"

the "Management Intensity Scale," the "Functional Status Scale," the "Environmental-Impact Scale," the "Somatic Vulnerability A Scale," the "Somatic Vulnerability B Scale," and the "Medication Management Intensity Scale." Prior to these subscales, exploration of content validity on a five subscale instrument yielded helpful, but not adequate information. Following the pilot study, 11 items were added to further define the character of asthma. Thus, the original five subscales and singular items used to measure factors were revised to an eight subscale instrument.

The psychometric study was conducted with 203 adults between the ages of 18 and 60 from a southwestern metroplex. Subjects were divided between males (18.2%) and females (81.8%). The mean age was 42.4 years, with all ages between 18 and 60 represented. The sample was largely minority, black, Hispanic, and Asian. Further, 57% were employed, reporting one to five people residing in the household, with a family income of $29,999 or less. More than half the subjects had no insurance, used the Emergency Room for urgent care visits, and their prescriptions were filled at the county hospital pharmacy.

Following data collection, questionnaires were coded, entered into a data file, and statistically analyzed using EQS 5.1 computer program for estimates of reliability and

factorial validity. Descriptive statistics were used to describe demographic and personal characteristic data.

Discussion of Findings

The main objective of this study was to develop an instrument to measure the character of asthma. The primary methods used were exploratory and confirmatory factor analyses. After exploring plausible factors, a three-factor model was determined to be the best fit. The confirmatory solution verified acceptable representation of the data. The findings of the study are discussed in relation to reliability and validity assessments.

Reliability

Reliability for each measure and the overall instrument was determined using Cronbach's coefficient alpha, K-R 20 for dichotomous measures and squared multiple correlation. All but two scales, the "Somatic Vulnerability A Scale" and the "Medication Management Intensity Scale" met Nunnally's (1978) criterion for coefficient alpha of 0.70 or higher. Recognizing the newness of the instrument, all scales were included in the three factor model to maintain theoretical congruency.

Item-to-scale correlations for all items were used to eliminate items with a correlation-to-scale below 0.3 and

greater than 0.70 (Nunnally, 1987). Three items were dropped from the "Symptom Intensity G and B Scales leaving 4 items. Four were removed from the "Functional Status Scale" with 6 items remaining. All items on the "Somatic Vulnerability B Scale" met the criteria, therefore 16 items were retained. Seven items remained on the "Somatic Vulnerability A Scale" when 2 of 9 items were dropped. After eliminating 5 items on the "Medication Management Intensity Scale," only 8 items remained.

Validity

Confirmatory factor analysis using maximum likelihood (ML) goodness-of-fit determined validity and fit of the model to the data. Some kurtotic distribution of data existed on half of the 8 subscales. With a sample size of 203 and eight observed and three latent variables, requirements for maximum likelihood were met. With skew and kurtosis from -1.0 to +1.0 distortion will not occur with ML (Muthen & Kaplan, 1985). With the exception of the "Functional Status Scale", which was -1.080, the range for kurtosis for all measures (-.733 to -0.057) fell within the range recommended by Muthen and Kaplan (1985). Maximum likelihood estimation was, therefore, determined to be an adequate analytical methodology for the data.

Conclusions and Implications

Reliability was adequate for six scales: the "Symptom Intensity G Scale", the "Symptom Intensity B Scale", the "Management Intensity Scale", the "Functional Status Scale", the "Environmental-Impact Scale", and the "Somatic Vulnerability B Scale". Although the "Somatic Vulnerability B Scale" and the "Medication Management Intensity Scale" were found to be somewhat deficient, both were included in the analysis of the three-factor Model 1 and Model 2. Both scales were believed to be in theoretical congruency with the character of asthma.

All hypothesized latent and formulated, summative observed variables in both models were associated with concepts constituting validity of the measures. Maximum likelihood estimation supported fit of the three factor model. The focal point in analyzing the models was in the extent to which the hypothesized model "fit" or, in other words, adequately described the sample data. Given the findings of an inadequate goodness of fit in the first confirmatory factor analysis, Model 1, the next step was to detect the misfit in the model. Assessment of the inadequacies included fit of individual parameters using the Lagrange Multiplier Test and Wald Test.

Chi-square is used in structural equation modeling to support how well the model fits the data rather than a test of significant difference between independent samples (Bollen, 1989). It is used to show how well the model's specifications describe the structure of relationships among the observed variables versus alternative hypothesis that these relationships are random or are small enough to be attributed to sampling error (Lavee, 1988). If the differences are small enough, then the null hypothesis is not rejected. Accordingly, the goal of significance testing in this study was a nonsignificant chi-square so that failure to reject would become a necessity.

Failure to reject the null hypothesis would mean lack of independence between the observed (actual) and expected data for the hypothesized models. Accordingly, failure to reject would mean that the model fit the data, and, therefore, represented a potential explanation of the data.. Notwithstanding, a failure to reject might acknowledge the existence of equivalent or superior models, particularly in an initial, exploratory study such as this one. A nonsignificant chi-square goodness of fit is desired.

A significant chi-square would mean rejection of the hypothesis, a rejection of the models or failure of the models to fit the data. The chi-square for Model 1 was

69.01 ($p < .001$) and 19.89 ($p = .069$) for Model 2. Model 2 was nonsignificant.

While the chi-square test is regarded as the appropriate test of significance for model fitting (Jöreskog & Sorbom, 1989), limitations of this test statistic have also been acknowledged. The problems are primarily related to the sensitivity of the chi-square significance test to sample size. Unlike chi-square, the goodness of fit index (GFI) is not affected by sample size. The GFI should be above 0.90 to indicate good fit of the model to the data (Brooke et al., 1988; Lavee, 1988). In this study the GFI was 0.924 for Model 1 and 0.978 for Model 2 indicating a high amount of variance and covariance jointly accounted for by the models.

Adjusted goodness-of-fit index (AGFI) adjusts the GFI for the degrees of freedom in the model and is independent of sample size (Bollen, 1989; Diamantopoulos, 1994; Lavee, 1988). An acceptable AGFI is one above 0.80 (Brooke et al,, 1988; Lavee, 1988). AGFI for Model 1 was 0.82 a difference of 0.10 from the GFI. For Model 2 the AGFI was 0.93, a difference of 0.04 from the GFI. Once again the models were supported when amount of variance and covariance jointly accounted for by the models was adjusted for degrees of freedom.

Root-mean-square-residual (RMR) is a measure of residual variance identifying the average amount of variance and covariance not accounted for by the model (Diamantopoulos, 1994; Lavee, 1988). The lower the RMR, the better the model fit. The closer to 0.00, the better with values less than 0.10 being desirable (Diamantopoulos, 1994). Model 1 had a RMR of 0.080 while Model 2 was 0.036. Normed fit index (NFI) compares the chi-square of the model to the chi-square for a null model that hypothesizes complete independence among measured variables. It is not affected by sample size or degrees of freedom. The NFI should be above or equal to 0.90 (Brooke et al., 1988). NFI for Model 1 was 0.784 and 0.938 for Model 2. Model 2 represented better fit.

Residuals and standardized residuals indicate which parameter specifications can be modified to improve fit (Bollen, 1989; Byrne, 1994). Residuals were small for both models and evenly distributed among the variables. If residuals were high, these variables could not be explained by the model. The range for Model 1 was -0.213 to 0.019 and 0.130 to 0.010 for Model 2.

In addressing the first hypothesis, the estimated degrees of homogeneity of items and scales for the Asthma Outcome Index (AOI) are greater than a Cronbach's alpha

coefficient of 0.70 in persons with asthma. Cronbach's alpha coefficient showed acceptable internal consistency in six of the eight scales. Squared multiple correlation for subscales of Models 1 and 2 ranged from 0.09 to 0.71.

The second hypothesis addresses the statistical fit of the measurement model to the observed data. Confirmatory factor analysis using EQS 5.1 revealed significant fit statistics implying causal relationships between all latent variables and their indicators for Model 2.

Six of the eight scales exhibited adequate reliability. Two scales did not. Validity was supported for Model 2. This is the first analysis of eight newly-developed measures and theoretical models. They must be tested on a different sample before the results of this study can be generalized.

Error is crucial to consider in research and theory construction. The use of SEM in the analysis of the AOI and the theoretical asthma model permitted estimation of error. If the asthma model was only estimated with traditional ordinary least squares regression without residual analysis, bias would be present. It is critical for researchers to understand error. Measured variables always have less than perfect reliability. Incorporating measurement error increases the validity of the model.

Finally, instrument development is a lengthy and difficult process. This study introduced a theoretical model identifying severity, self-management, and illness intensity as factors describing the character of asthma. Results are encouraging and indicate that not only does the AOI show promise as defining the character of asthma, but that an instrument with different types of questions can be reliable and valid. Replication of this study is needed to confirm or disconfirm these study results. Information from future research endeavors will only improve the success of management interventions in the area of asthma.

Recommendations for Further Study

Possibly the greatest potential value of the present research lies in its ability to stimulate further investigation. Although results obtained from the EQS 5.1 analysis provided support for the psychometric adequacy of the Asthma Outcome Index, collection of additional reliability and validity data are warranted. The empirical support for Model 2 does not imply that other models could not exist or could not have produced equal good or better results. The present model needs to be compared with other models containing additional paths. Such empirical verification of conceptual models for the character of asthma may suggest new directions for productive

intervention strategies, which in turn would require validation.

The following recommendations for future study were identified:

1. Refinement of the Asthma Outcome Index and reduction of the number of indicators per construct with additional reliability and validity data are warranted.

2. Correlations occurring within the constructs, severity, self-management, and illness intensity are suggestive of a need for higher order or second order factor analysis.

3. Consider several alternative models. Often knowledge in an area is not detailed enough to provide a single specification of a model. Estimating several models permits researchers to explore plausible structures. This best comparison allows us to determine the model with the best fit, rather than attempt to assess a single model's fit in the absolute sense (Bollen, 1993).

4. Test and retest reliability estimation for assessment of stability of the Asthma Outcome Index should be explored to identify to what extent these constructs predict themselves over time.

5. Different asthma populations should be tested who differ with regard to demographic characteristics to

identify if the measurement model is invariant across groups.

6. Evaluate the feasibility of demographic characteristics as a latent construct.

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APPENDIX A

Human Subjects Review Form

TEXAS WOMAN'S
UNIVERSITY
DENTON/DALLAS/HOUSTON

HUMAN SUBJECTS
REVIEW COMMITTEE
P.O. BOX 22939
Denton, TX 76204-0939
Phone: 817/898-3377

September 11, 1995

Diane Elizabeth Schull
2929 Sundial Drive
Dallas, Tx 75229

Dear Diane Elizabeth Schull: Social Security #: [redacted]

Your study entitled "Characterization of Asthma in Adults: A Comprehensive Instrument" has been reviewed by a committee of the Human Subjects Review Committee and appears to meet our requirements in regard to protection of individuals' rights.

Be reminded that both the University and the Department of Health and Human Services (HHS) regulations typically require that agency approval letters and signatures indicating informed consent be obtained from all human subjects in your study. These are to be filed with the Human Subjects Review Committee. Any exception to this requirement is noted below. This approval is valid one year from the date of this letter. Furthermore, according to HHS regulations, another review by the Committee is required if your project changes.

Special provisions pertaining to your study are noted below:

____ The filing of signatures of subjects with the Human Subjects Review Committee is not required.

____ Other:

_X_ No special provisions apply.

Sincerely,

Glenn Englbrecht

Chair
Human Subjects Review Committee - Denton

cc: Graduate School
Dr. Margaret Beard, Nursing
Dr. Carolyn Gunning, Nursing

SOUTHWESTERN
THE UNIVERSITY OF TEXAS
SOUTHWESTERN MEDICAL CENTER
AT DALLAS

Institutional Review Board

July 10, 1995

Diane E. Schull
Department of Internal Medicine

RE: IRB FILE # 0795 29000
Characterization of Asthma in Adults: Comprehensive Instrument

Dear Ms. Schull:

On July 10, 1995, the Institutional Review Board considered the above-referenced study and approved the protocol and consent form as enclosed. Please use this approved consent form and destroy all other drafts or undated copies. The annual review of this study is scheduled for July 1996.

University and Federal regulations require that written consent be obtained from all human subjects in your studies. The consent form should be kept on file for a period of three years past completion of the study. A copy of the consent form should be given to each participant in your study. Also, the University attorneys have asked us to remind investigators to put a copy of the consent form in the subject's medical record. Investigators should file the original, executed copy of the consent form with their records of the protocol.

The HHS regulations require you to submit annual and terminal progress reports to our Institutional Review Board and to receive continuing review of your activity annually by this Board. Please report to the Board any deaths or adverse reactions occurring during the study. It is required that you keep the IRB informed of such events in order to prevent sanctions being placed on the institution. Furthermore, if you require a modification contact me in order that appropriate review and approval can be made prior to implementing the change.

If you have any questions related to this protocol or to the Institutional Review Board please contact me at 648-2258 or Romelle Hase at 648-3060.

Sincerely,

Perrie M. Adams, Ph.D.
Associate Dean for Research
Chairman
Institutional Review Board

PMA/rh
Enclosure

5323 Harry Hines Boulevard, 88.406 / Dallas, Texas 75235-9007 / (214)648-3060

Consent Forms

TITLE: Characterization of Asthma in Adults: A Comprehensive Instrument

I. Background: Since there is no agreed upon standard for assessing the disease severity in asthma, creative approaches are necessary to more precisely define parameters. Correct assessment of disease severity is central to assessing the health status and progression of the disease, establishing standards for treatment and determining requirements for individualized treatment plans. Outcome measures need to include multiple health status and physiological measurements including process and impact measures related to the efficacy and effectiveness of interventions. Consequently, the newly constructed instrument measure disease severity as an outcome measure will be tested in the area of asthma.

II. Purpose: The purpose of this study is to develop, refine and psychometrically estimate the properties of the researcher-developed instrument, the Asthma Outcome Index (AOI).

III. Recruitment of Subjects: All subjects will be approached by the researcher. A purposive sampling technique will be employed to locate 300 study participants. Purposive sampling involves the conscious selection by the researcher of certain subjects, for example, asthmatics. Each participant, whether previously known to the researcher or not, will be free and capable of choosing to participate in the study. Informed consent will be obtained from all subjects verbally and in writing after reading a written explanation of the study requirements in the form of a letter outlining the purpose, potential risks, potential benefits and alternatives. The name, address and office telephone number of the researcher will be listed in the letter. Each subject will be given a copy of the consent form. A statement indicating availability of the researcher to answer questions or concerns prior to, during and post study will be included.

IV. Inclusion of Subjects:
1. Diagnosis of asthma made by a physician.
2. Subjects will be between 18 and 55 years of age.
3. Subjects are able to read and write English.

V. Exclusion of Subjects: Subjects who are unable to give consent.

VI. Setting of the Study: The setting of the data collection will be a 940 bed, publicly supported hospital in the Southwest with an affiliated medical school and associated physicians in the community. People diagnosed with asthma will be seen in the inpatient, outpatient, emergency department and community based settings.

VII. Sources of Research Material: The source of research material will be the researcher-developed instrument, Asthma Outcome Index (AOI). The data obtained from this questionnaire will be used only for research purposes in the development of a reliable and valid instrument.

VIII. Potential Risks: No permanent discomfort or harm is anticipated from responding to the questionnaire.

IX. Potential Benefits: Benefits from participation may include the possibility of increased awareness of one's health status related to asthma.

X. Special Precautions: Not applicable.

XI. Procedures to Maintain Confidentiality: The name of the subject will not appear on the questionnaire. The answers obtained from the questionnaire will not be revealed and will not be released to anyone other than the researcher. Confidentiality of the data will be maintained by using a study code. Consent forms and data will be secured in a locked file and destroyed at the end of the study.

THE UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER AT DALLAS
SUBJECT CONSENT TO PARTICIPATE IN RESEARCH

TITLE OF STUDY: Characterization of Asthma in Adults: A Comprehensive Instrument

SPONSOR:

INVESTIGATORS:	OFFICE PHONE #	NIGHT/WEEKEND #
1. Diane E. Schull, RN MS	(214) 590-7908	(214) 590-8000
2.		
3.		
4.		

You are being asked to participate in a research study. Persons who participate in research are entitled to certain rights. These rights include but are not limited to the subject's right to:

1. Be informed of the nature and purpose of the research;

2. Be given an explanation of the procedures to be followed in the research, and any drug or device to be utilized;

3. Be given a description of any attendant discomforts and risks reasonable to be expected;

4. Be given a disclosure of any benefits to the subject reasonable to be expected, if applicable;

5. Be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, their relative risks and benefits;

6. Be informed of the alternatives of medical treatment, if any, available to the subject during or after the experiment if complications arise;

7. Be given an opportunity to ask any questions concerning the research and the procedures involved;

8. Be instructed that consent to participate in the research may be withdrawn at any time, and the subject may discontinue participation without prejudice;

9. Be given a copy of the signed and dated consent form;

10. And be given the opportunity to decide to consent or not to consent to participate in research without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

IRB File # 0795 29000

Date Approved JUL 10 1995

(02/93)

SECTION A *Attach this page as page 2 of your HSRC application*

All research involving human subjects will be reviewed. Research is defined as an activity designed to test an hypothesis, draw conclusions, or contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. Human subject is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or 2) identifiable private information. Research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues which are individually identifiable also is included within the term "research involving human subjects." Studies placing human subjects at risk will receive more extensive review. An individual is considered to be at risk if he/she may be exposed to the possibility of harm -- physical, psychological, social or other.

"Risk" includes, but is not limited to, the possibility of public embarrassment, improper release of data, physical harm, physical discomfort, fatigue, boredom, loss of privacy, loss of time, and monetary costs (e.g., for transportation, childcare, and time lost from work). The most obvious examples of placing subjects at risk include the experimental use of the following procedures: surgical and biopsy procedures; the administration of drugs or radiation; the use of indwelling catheters or electrodes; the requirement of unusual physical exertion; subjection to deceit, public embarrassment, and/or humiliation. Also consider as risks: discomfort, anxiety, harassment, invasion of privacy, or emotional distress resulting from fear of self-disclosure, introspection, fear of the unknown, interacting with strangers, fear of eventual repercussions, and anger at the type of questions being asked.

If an activity will expose an individual to risk, then the committee will wish to assure itself that (a) the rights and welfare of the individuals are adequately protected, (b) the methods used to obtain informed consent are adequate and appropriate, and (c) the risks to the individual are out-weighed by the potential benefit to the individual or society or by the importance of the knowledge to be gained.

Respond by checking one answer for each of the following		YES	NO
(1)	With respect to the above criteria the human subjects involved are at risk	☐	☒
(2)	Students will be used as subjects	☐	☒
(3)	Experimental drugs will be used	☐	☒
(4)	Experimental devices will be used	☐	☒
(5)	Non-English speaking subjects will be used	☐	☒
(6)	Minors will be used (younger than 18 years)	☐	☒
(7)	Subjects with mental disabilities will be used	☐	☒
(8)	Prisoners and/or incarcerated subjects will be used	☐	☒
(9)	Institutionalized subjects will be used	☐	☒
(10)	Radiation will be used	☐	☒

FACT SHEET-PATIENT

Project Title: Characterization of Asthma in Adults: A Comprehensive Instrument

Principal Investigator: Diane E. Schull
Telephone Number: (214) 590-7908

PURPOSE: By learning from you today, the researcher hopes to improve the delivery of care to people with asthma through the development of an instrument that will measure the outcomes of treatments for your asthma.

PLAN: The researcher will ask you to complete a questionnaire and may interview you to obtain information regarding your asthma. I value what you think and hope you will participate in the research. Participation in this study is voluntary.

RISK, STRESS, OR DISCOMFORT
Your answers will not be revealed and will not be released to anyone other than the researcher. So that no one will know who you are, your name is not on the interview form. Data regarding your asthma will be secured in a locked file and destroyed at the end of the study.

Whether or not you take part in this study, your health care will not be affected.

If you have any questions about the research or about your rights as a subject, we want you to ask us. If you have questions or concerns about the way this research has been conducted, contract the Texas Woman's University, Office of Research and Grants Administration during office hours (214) 898-3375.

I have reviewed this fact sheet and have had a chance to ask questions. I agree to participate in this study. I give permission for the medical record to be reviewed.

Thank you.

_____ _____
SIGNATURE OF SUBJECT DATE

_____
SIGNATURE OF INVESTIGATOR

APPENDIX C

Agency Permission Letters and Publisher's Consent to Use Copyrighted Material

USE OF COOPERATING INSTITUTION
Institutional Review Board

If this research involves CHILDREN'S MEDICAL CENTER (CMC), PARKLAND MEMORIAL HOSPITAL (PMH), ZALE LIPSHY UNIVERSITY HOSPITAL (ZLUH), please complete this two-page form:

Study Title: Characterization of Asthma in Adults: A Comprehensive Instrument

Principal Investigator: Diane Elizabeth Schull Phone/Beeper: 21148

Sponsor: Donald A. Kennerly MD PhD

Research Coordinator: Diane E. Schull Phone/Beeper: 21148

Hospital: Parkland Memorial Hospital

♦ ♦

Projected duration of study: From: 7-30-95 To: 7-30-96

Total # of patients in study: 300

Source of patients (e.g, clinic, ER, CCU): OPC ER and Inpatient

Is this approval for recruitment of subjects ONLY?

X Yes (Proceed to signatures on bottom of page 2)

____ No (Continue and complete all information requested)

Will patients be hospitalized for research purposes only?

____ Yes (Estimate # of days: ____)

____ No

As a result of participating in this study, the projected # of patients requiring:

	INPATIENT SERVICES	OUTPATIENT SERVICES
CMC:		
PMH:		
UH:		

(10/93)

What are the incremental resources, e.g., surgical procedures, medications, tests, extended length of stay, required to support this study? (This represents all goods and services over and above what would be considered generally accepted treatment, or what is being done as part of the study that would be different than normally done for/to the patient.) PLEASE BE SPECIFIC - FAILURE TO COMPLETE THIS SECTION WILL DELAY INSTITUTIONAL APPROVAL OF THE STUDY.

Not applicable

Is the patient to be billed?

_____ Yes, all charges to be billed to patient/insurance company

_____ No, patient will not be billed at all

_____ Partial billing of patient will occur [What services (e.g., medications, devices, procedures) will NOT be billed]?

Not applicable

Is there any external funding available to the institution, e.g., grant monies, manufacturer-provided goods or services, other than the patient bill?

_____ Yes (Identify source, amount, and how it will be accessed by the institution):

Not applicable

_____ No

R. Anderson
Authorized Hospital Signature

7/12/95
Date

Duane E. Knuth
Principal Investigator Signature

7/12/95
Date

(10/93)

March 18, 1996

Our Ref: 96-122

Ms. Diane Devine
Marcel Dekker, Inc.
270 Madison Avenue
New York, New York 10016

Dear Ms. Devine,

As per our conversation, I am requesting permission to use one figure and two tables from the book Severe Asthma: Pathogenesis and Clinical Management, (1996) edited by Stanley J. Szefler and Donald Y. M. Leung. The figure is in Chapter 1, page 3 and is titled *A framework of severity of chronic illness (Figure 1)*. The first table is in Chapter 1, page 4 and is titled *Comparison of FEV1 Criteria for Assessing Asthma Severity (Table 1)*. The second table is in Chapter 17, page 456 and is titled *Measuring Adherence to Asthma Therapy (Table 5)*. The authors are Stein, Corre and Rand, respectively.

I am a doctoral candidate at Texas Woman's University, Denton, Texas and would include the figure and tables requested as part of Chapter 2 of my dissertation. Chapter 2 is a review of the literature and my dissertation topic is Asthma Severity. The chairperson of my dissertation committee is Margaret Beard, PhD and can reached at (817) 898-2401.

Please contact me if I can answer any further questions regarding my request.

Sincerely,

Diane Schull

Diane Schull
2929 Sundial Drive
Dallas, Texas 75229
(214) 484-3504 home
(214) 648-3004 work
(214) 648-9100 fax

PERMISSION GRANTED with the understanding that proper credit be given to Marcel Dekker Inc.
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Diane Devine-Mount 3/19/96

APPENDIX D

Content Experts

Content Experts

1. Compton Broders, MD, Chief on Staff and Medical Director of Emergency Services, Presbyterian Hospital, Dallas, Texas

2. Nancy Finnerty, MD, Allergist in Private Practice, Dallas, Texas

3. Sharon Kowatch, MS, RN, FNP, Nurse Practitioner, Presbyterian Hospital, Dallas, Texas

4. Gretchen Williams, RRT, Respiratory Therapist, Asthma Program Coordinator, Baylor University Medical Center, Dallas, Texas

APPENDIX E

Instrument

ASTHMA OUTCOME INDEX (AOI)

NAME: _____

DATE: _____

Patient ID:_____

ASTHMA OUTCOME INDEX (AOI)

DIRECTIONS: This questionnaire contains statements about your asthma. Please respond to each item as accurately as possible and try not to skip any item.

1. Age:_____

2. Gender:
   _____ Male
   _____ Female

3. Race/Ethnicity
   ___Asian
   ___Black
   ___Hispanic
   ___Native American
   ___White
   ___other_____

4. How many people live in your home?_____

5. How many children under the age of 16 live with you?_____

6. Do you work outside of the home: _____yes _____no
   If yes, what kind of work do you do?_____

7. What is the approximate total income in your home?
   ___less than $15,000
   ___$16,000-29,999
   ___$30,000-49,999
   ___$50,000-79,999
   ___greater than $80,000

8. What is the highest level of education that you have completed?
   ___some high school (grade 0-11)
   ___high school graduate or GED
   ___technical or trade school
   ___some college
   ___college graduate
   ___post-graduate study

9. How do you pay for your hearth care?
   ___self-pay (no insurance)
   ___Medicaid
   ___Medicare
   ___health insurance, do you have a co-payment? ___no ___yes
   ___don't know

10. Where do you usually get your prescriptions filled?
    ___private pharmacy
    ___hospital pharmacy

11. In general, would you say your health is:
___excellent
___very good
___good
___fair
___poor

12. Compared to one year ago, how would you rate your general health now?
___much better than one year ago
___somewhat better than one year ago
___about the same
___somewhat worse than one year ago
___much worse than one year ago

13. Have you ever been told by a doctor that you have asthma?
___no ___yes

14. Have you ever been told by a doctor that you have COPD or emphysema? ___no ___yes

15. Have you ever been told by a doctor that you have chronic bronchitis? ___no ___yes

16. How long have you had asthma?
___less than 1 year
___1-5 years
___6-10 years
___11-20 years
___21-30 years
___greater than 30 years

17. About how old were you when you asthma began?
___less than 10 years old
___10-19 years old
___20-29 years old
___30-39 years old
___40 years old or older

18. During the last year, where have you been treated for your asthma? (check all answers that are true)
___in an emergency room
___in a doctor's office or clinic
___over the telephone by a doctor
___overnight treatment in the hospital as a patient
___treat myself at home

19. Where were you treated for your last asthma attack?
___in an emergency room
___in a doctor's office
___over the telephone with a doctor
___in the hospital as a patient
___treated myself at home

20. Have you ever been treated for your asthma by any of the following? (check all answers that are true)
___Allergist
___Family practice physician
___General practice physician
___Internist
___Pediatrician
___Pulmonologist

21. How do you feel about the information your doctor or his/her staff have given you about what to do for your asthma?
___they have given me very little information about what to do
___they told me some things, but I could use more information
___they told me everything I want to know

22. Over the past year, has your asthma
___gotten better
___stayed about the same
___gotten worse

23. During the past month, has your asthma interfered with your work, school, or other daily activities?
___not at all
___1-3 days
___407 days
___2-3 weeks
___almost every day

24. How many times have you had urgent and unplanned visits to your doctor, clinic, or emergency room during the last year?
___none
___1-2 visits
___3-5 visits
___greater than 5 visits

25. How many times have you been admitted to the hospital during the last year for asthma?
___none
___1
___2
___3 or more

26. During your whole life, how many times have you been intubated and put on a ventilator/breathing machine for your asthma?
___never
___1 time
___2 or more times

Do you have any of the following problems?

27. Hay fever or nasal allergy
___none
___once a year
___two to three times a year
___more than four times a year or all the time
___don't know

28. Sinus infections
___never
___occasional
___frequent

29. Heartburn
___never
___sometimes
___frequent
___don't know

30. Have you ever had an asthma reaction to aspirin or pain medication (Advil, Motrin, Aleve, Naprosyn)?
___no
___yes
___don't know

31. Has a doctor ever told you that you had any of the following conditions (check all answers that are true)
___serious heart problems
___diabetes
___hypertension
___other, please list
_____
_____
_____
_____
_____

32. Do you currently smoke?
___no ___yes
If yes how many packs per day?_____
In the past, how much did you smoke?
___never
___yes
If yes, for how many years_____ how many packs_____

33. Do you live with people who smoke? ___no ___yes

34. Do you work with people who smoke? ___no ___yes

35. If you currently smoke would you like help to stop smoking?
___no ___yes

36. Which things listed below make your asthma worse?
(check all answers that are true)
___changes in the weather
___grass pollen
___tree pollen
___weed pollen
___pollution (ozone)
___dogs
___cats
___cockroaches
___smoke
___sinus infections/colds
___dust

___molds
___stress
___exercise
___medications

37. Which of the following are true statements:
(check all answers that are true)
___I use fans in my home
___I own a dog that comes into the house
___I own a dog that stays outside
___I own a cat that comes into the house
___I own a cat that stays outside
___there are rugs or carpet in my home
___there are draperies or curtains in my home
___I have a feather pillow or comforter
___there is mold in my bathroom or basement
___I often see cockroaches in my home

38. Which of the following are true statements:
(check all answers that are true)
___I usually use a spacer with my inhaler(s)
___I usually use a peak flow meter
___I use the hot water setting in my laundry
___I use dust covers on my mattress
___I use dust covers on my pillows
___I manage my asthma myself
___I use a care plan given to me by a doctor or nurse
___I recognize things that make my asthma worse
___I rest when I have symptoms
___I drink plenty of fluids
___I stay calm during an asthma attack
___I go to the Emergency Room
___I call the doctor
___I take medications when they are appropriate
___I use medications before exercise
___I know the early warning signs of asthma

39. Have you had skin test or blood tests for allergies?
___no ___yes

40. If yes, was your allergy test positive?
___no ___yes

41. If you had a positive allergy test were the results:
___strongly positive
___moderately positive
___do not know

42. How many different medicines do you take for your asthma? ___

43. During the last 30 days, how many days did you usually feel well?
___1-5 days
___6-10 days
___11-15 days
___16-20 days
___21-25 days
___26-30 days

The next group of questions will ask you about the symptoms you have had during the past 30 days.

44. During the last 30 days, on your typical or average days, which of the following symptoms did you have?

	None	Very Little	Frequent	All the time
1. Wheezing	1	2	3	4
2. Shortness of breath	1	2	3	4
3. Cough	1	2	3	4
4. Chest tightness	1	2	3	4
5. Fatigue	1	2	3	4
6. Irritability	1	2	3	4
7. Afraid or nervous	1	2	3	4

45. During the last 30 days, on your bad or worse than average days, which of the following symptoms did you have?

	None	Very Little	Frequent	All the time
1. Wheezing	1	2	3	4
2. Shortness of breath	1	2	3	4
3. Cough	1	2	3	4
4. Chest tightness	1	2	3	4
5. Fatigue	1	2	3	4
6. Irritability	1	2	3	4
7. Afraid or nervous	1	2	3	4

46. During the last 30 days, how many times did you awaken during the night because of your asthma?
___never
___occasionally
___many nights
___every night

47. During the last 30 days, how many times did you awaken during the night to use your inhaler?
___never
___occasionally
___many nights
___every night

48. Please list all the medicines you take for your asthma, please include when you take them and how much (if you need help with this please ask the doctor or nurse)

Medicine	How much	How often	As needed

Have you taken oral steroid medicine during the last month?
___no
___yes
___don't know

Do you use a nebulizer at home? ___no ___yes
If so, how often_____

DIRECTIONS: For each of the statements shown below, please indicate how much you agree or disagree with it by circling the most accurate answer.

	Always True	Sometimes True	Not True
49. I hate having asthma.	2	1	0
50. I cannot control whether my asthma gets worse or better.	2	1	0
51. If my asthma gets worse, it is because I have not taken proper care of myself.	2	1	0
52. Luck plays a big part in determining how well I do with my asthma.	2	1	0
53. If it's meant to be, I will stay healthy.	2	1	0
54. Asthma controls my life.	2	1	0
55. No matter what I do, I probably will have asthma attacks.	2	1	0
56. Doctors, nurses, and other health professionals are responsible for my health.	2	1	0
57. I worry that I might die during an asthmatic attack.	2	1	0
58. If I take the right actions, I can prevent most asthma attacks.	2	1	0
59. Asthma interferes with my social activities.	2	1	0
60. Asthma interferes with my family.	2	1	0
61. I stay calm when I have breathing problems.	2	1	0
62. I take it easy the day following an asthma attack.	2	1	0
63. I worry about having asthma.	2	1	0

	Always True	Sometimes True	Not True
64. Asthma interferes with things I want to do.	2	1	0
65. I stay away from things that make my asthma worse.	2	1	0
66. I do breathing exercises when I have trouble breathing.	2	1	0
67. I try to make myself relax when I have breathing problems.	2	1	0
68. I feel sad about having asthma.	2	1	0
69. I ask for help from other people when I first notice any breathing problems.	2	1	0
70. People treat me better when I have an asthmatic attack.	2	1	0
71. I have a spouse, friend, or significant other who helps and supports me with my asthma.	2	1	0
72. I don't like having to take medicines for my asthma.	2	1	0
73. I feel I can take care of my asthma myself.	2	1	0

DIRECTIONS: The following items are things you might do during the day. Does you asthma limit you in these activities? If so how much?

	Yes Alot	Yes A Little	Not At All
74. Running, lifting of heavy objects, or strenuous sports.	2	1	0
75. Moving a table, pushing a vacuum cleaner, bowling, playing golf.	2	1	0
76. Lifting or carrying groceries.	2	1	0
77. Climbing several flights of stairs.	2	1	0
78. Climbing one flight of stairs.	2	1	0

	Yes Alot	Yes A Little	Not At All
79. Bending, kneeling or stooping.	2	1	0
80. Walking more than a mile.	2	1	0
81. Walking several blocks.	2	1	0
82. Walking one block.	2	1	0
83. Bathing or dressing yourself.	2	1	0

DIRECTIONS: With your pen or pencil draw a line where you feel your quality of life is at this moment.

84. _____

BAD GOOD

To be completed by the physician or health care worker.

85. FEV1 (baseline)
___>80% predicted
___<80% predicted
___<60% predicted
___<40% predicted

APPENDIX G

Reformulated Scales, Items, Frequencies, Means, Standard Deviations, Skewness, and Kurtosis

SYMPTOM INTENSITY G SCALE

	Percentage	Mean	Std.	Skewness	Kurtosis
During the last 30 days, on your **typical** or **average** days, which of the following symptoms did you have?					
1. Wheezing		1.690	0.910	-0.139	-0.802
Code: 0 None	9.9				
1 Very Little	32.0				
2 Frequent	37.4				
3 All the time	20.7				
2. Shortness of Breath		1.906	0.848	-0.115	-1.012
Code: 0 None	2.9				
1 Very Little	32.o				
2 Frequent	36.5				
3 All the time	28.6				
3. Cough		1.458	0.886	0.085	-0.698
Code: 0 None	13.8				
1 Very Little	39.4				
2 Frequent	33.9				
3 All the time	12.9				
7. Fear		1.433	1.005	0.229	-1.019
Code: 0 None	18.2				
1 Very Little	39.9				
2 Frequent	22.2				
3 All the time	19.7				

SYMPTOM INTENSITY B SCALE

	Percentage	Mean	Std.	Skewness	Kurtosis
During the last 30 days, on your **bad** or **worse** than average days, which of the following symptoms did you have?					
1. Wheezing		2.315	0.867	-1.120	0.417
Code: 0 None	4.9				
1 Very Little	11.8				
2 Frequent	30.1				
3 All the time	53.2				
2. Shortness of Breath		2.310	0.831	-0.845	-0.425
Code: 0 None	1.9				
1 Very Little	17.7				
2 Frequent	27.6				
3 All the time	52.8				
3. Cough		2.103	0.930	-0.730	-0.422
Code: 0 None	6.9				
1 Very Little	17.7				
2 Frequent	33.5				
3 All the time	41.9				
7. Fear		1.995	1.041	-0.654	-0.806
Code: 0 None	12.3				
1 Very Little	17.2				
2 Frequent	29.1				
3 All the time	41.4				

ENVIRONMENTAL-IMPACT SCALE

	Percentage	Weighted Mean	Std.	Skewness	Kurtosis
36. Which things listed make your asthma worse? (Sensitivities) 37. Which of the following are true statement? (Exposures)					
Sensitivity to weather.		1.813	0.584	-2.811	5.963
Code: 1(x2)Yes	90.6				
0(x2)No	9.4				
Sensitivity to grass, tree and weed pollen.		1.685	1.246	-0.265	-1.568
Code: 0 None	28.1				
1 One of them	13.8				
2 Two of them	19.7				
3 All of them	38.4				
Sensitivity to pollution.		1.281	0.962	-0.589	-1.669
Code: 1(x2)Yes	64.0				
0(x2)No	36.0				
Sensitivity and exposure to a dog living in the house.		0.138	0.508	3.427	9.844
Code: 1(x2)Yes	6.9				
0(x2)No	93.1				

	Percentage	Weighted Mean	Std.	Skewness	Kurtosis
Sensitivity and exposure to a cat living in the house.		0.049	0.311	6.180	36.549
Code: 1(x2)Yes	2.5				
0(x2)No	97.5				
Sensitivity and exposure to cockroaches.		0.443	0.833	1.350	-0.179
Code: 1 Yes	22.2				
0 No	77.8				
Sensitivity to colds.		0.911	0.822	0.166	-1.501
Code: 0 None	38.4				
1 Some of the time	32.0				
2 All of the time	29.6				
Sensitivity to dust.		1.729	1.099	0.171	-0.630
Code: 0 None	14.3				
1 Some of the time	34.4				
2 All of the time	51.3				
Sensitivity to molds		0.128	0.335	2.242	3.059
Code: 1 Yes	12.8				
0 No	78.2				

FUNCTIONAL STATUS SCALE

	Percentage	Mean	Std.	Skewness	Kurtosis
The following items are things you might do during the day. Does your asthma limit you in these activities? If, so how much?					
74. Running, lifting of heavy objects, or strenuous sports.		1.557	0.66	-1.216	0.220
Code: 2 Yes, alot	65.5				
1 Yes a little	24.6				
0 Not at all	9.9				
75. Moving a table, pushing a vacuum cleaner, bowling, playing golf.		1.296	0.778	-1.217	-0.570
Code: 2 Yes, alot	49.3				
1 Yes a little	31.0				
0 Not at all	19.7				
77. Climbing several flights of stairs.		1.517	0.699	-1.116	-0.102
Code: 2 Yes, alot	63.6				
1 Yes a little	24.6				
0 Not at all	11.8				

	Percentage	Mean	Std.	Skewness	Kurtosis
79. Bending, kneeling or stooping.		0.98	0.808	0.036	-1.467
Code: 2 Yes, alot	31.5				
1 Yes a little	35.0				
0 Not at all	33.5				
82. Walking one block.		0.956	0.858	0.085	-1.639
Code: 2 Yes, alot	34.5				
1 Yes a little	26.6				
0 Not at all	38.9				
83. Bathing or dressing yourself.		0.680	0.833	0.660	-1.241
Code: 2 Yes, a lot	23.7				
1 Yes a little	20.7				
0 Not at all	23.6				

MANAGEMENT INTENSITY SCALE

	Percentage	Mean	Std.	Skewness	Kurtosis
Code: 0=No					
1=Yes					
38. Which of the following are true statements (Check all answers that are true)					
2. I usually use a peak flow meter.		0.4773	0.50	0.109	-2.008
Yes	47.3				
No	52.7				
7. I use a care plan given to me by a doctor or nurse.		0.512	0.501	-0.050	-2.018
Yes	51.2				
No	48.8				
8. I recognize things that make my asthma worse.		0.714	0.453	-0.956	-1.097
Yes	71.4				
No	28.6				
9. I rest when I have symptoms.		0.744	0.438	-1.126	-0.740
Yes	74.4				
No	25.6				
10. I drink plenty of fluids.		0.764	0.426	-1.250	-0.443
Yes	76.5				
No	23.5				

	Percentage	Mean	Std.	Skewness	Kurtosis
Code: 0=No					
1=Yes					
11. I stay calm during an asthma attack.		0.621	0.486	-0.501	-1.766
Yes	62.1				
No	37.9				
12. I go to the Emergency Room.		0.665	0.473	-0.705	-1.519
Yes	66.5				
No	33.5				
14. I take medications when they are appropriate.		0.778	0.412	-1.350	-0.179
Yes	77.8				
No	22.2				
15. I use medications before exercise.		0.458	0.499	0.169	-1.991
Yes	54.2				
No	45.8				
16. I know the warning signs of asthma		0.680	0.468	-0.777	-1.411
Yes	68.0				
No	32.0				

SOMATIC VULNERABILITY A SCALE

	Percentage	Mean	Std.	Skewness	Kurtosis
Code: 2=Always true 1=Sometimes true 0=Not true					
58. If I take the right actions, I can prevent most asthma attacks.		0.749	0.589	0.125	-0.479
Always true	7.9				
Sometimes true	59.1				
Not true	33.0				
61. I stay calm when I have breathing problems.		0.749	0.606	0.183	-0.539
Always true	8.9				
Sometimes true	57.1				
Not true	34.0				
62. I take it easy the day following an asthma attack.		0.621	0.724	0.718	-0.775
Always true	14.3				
Sometimes true	33.5				
Not true	52.2				
65. I stay away from things that make my asthma worse.		0.635	0.656	0.548	-0.676
Always true	9.9				
Sometimes true	43.8				
Not true	46.3				

	Percentage	Mean	Std.	Skewness	Kurtosis
Code: 2=Always true 1=Sometimes true 0=Not true					
66. I do breathing exercises when I have trouble breathing.		0.961	0.814	0.073	-1.485
Always true	31.0				
Sometimes true	34.0				
Not true	35.0				
67. I try to make myself relax when i have breathing problems.		0.340	0.595	1.567	1.380
Always true	6.4				
Sometimes true	21.2				
Not true	72.4				
71. I have a spouse, friend or significant other who helps and supports me with my asthma.		0.744	0.835	0.512	-1.376
Always true	25.1				
Sometimes true	24.1				
Not true	50.8				

SOMATIC VULNERABILITY B SCALE

	Percentage	Mean	Std.	Skewness	Kurtosis
Code: 2=Always true 1=Sometimes true 0=Not true					
49. I hate having asthma.		1.837	0.396	-2.315	4.686
Always true	84.8				
Sometimes true	14.3				
Not true	0.9				
50 I cannot control whether my asthma gets worse or better.		1.049	0.695	-0.066	-0.912
Always true	26.6				
Sometimes true	51.7				
Not true	21.7				
52. Luck plays a big part in determining how well I do with my asthma.		0.498	0.754	1.129	-0.301
Always true	15.8				
Sometimes true	18.2				
Not true	66.0				
53. If its meant to be, I will stay healthy.		0.951	0.921	0.098	-1.825
Always true	40.0				
Sometimes true	15.2				
Not true	44.8				

	Percentage	Mean	Std.	Skewness	Kurtosis
Code: 2=Always true 1=Sometimes true 0=Not true					
54. Asthma controls my life.		0.887	0.766	0.195	-1.267
Always true	24.1				
Sometimes true	40.4				
Not true	35.5				
55. No matter what I do, I probably will have asthma attacks.		0.931	0.748	0.113	-1.199
Always true	24.7				
Sometimes true	43.8				
Not true	31.5				
56. Doctors, nurses and other health professionals are responsible for my health.		0.429	0.703	1.338	0.328
Always true	12.3				
Sometimes true	18.2				
Not true	69.5				
57. I worry that I might die during an asthma attack.		1.039	0.763	-0.067	-1.275
Always true	31.0				
Sometimes true	41.9				
Not true	27.1				
59. Asthma interferes with my social activities.		1.187	0.734	-0.309	-1.094
Always true	37.9				
Sometimes true	42.9				
Not true	19.2				

	Percentage	Mean	Std.	Skewness	Kurtosis
Code: 2=Always true 1=Sometimes true 0=Not true					
60. Asthma interferes with my family.		0.995	0.799	0.009	-1.432
Always true	31.5				
Sometimes true	36.5				
Not true	32.0				
63. I worry about having asthma.		1.438	0.724	-0.888	-0.569
Always true	57.6				
Sometimes true	28.6				
Not true	13.8				
64. Asthma interferes with things I want to do.		1.315	0.724	-0.560	-0.919
Always true	46.8				
Sometimes true	37.9				
Not true	15.3				
68. I feel sad about having asthma.		1.251	0.8009	-0.490	-1.304
Always true	48.3				
Sometimes true	28.6				
Not true	23.1				

	Percentage	Mean	Std.	Skewness	Kurtosis
Code: 2=Always true 1=Sometimes true 0=Not true					
69. I ask for help from other people when I first notice any breathing problems.		0.847	0.791	0.279	-1.347
Always true	24.6				
Sometimes true	35.5				
Not true	39.9				
70. People treat me better when I have an asthma attack		0.739	0.787	0.499	-1.216
Always true	21.2				
Sometimes true	31.5				
Not true	47.3				
72. I don't like having to take medicines for my asthma.		1.074	0.861	-0.143	-1.642
Always true	40.9				
Sometimes true	25.6				
Not true	33.5				

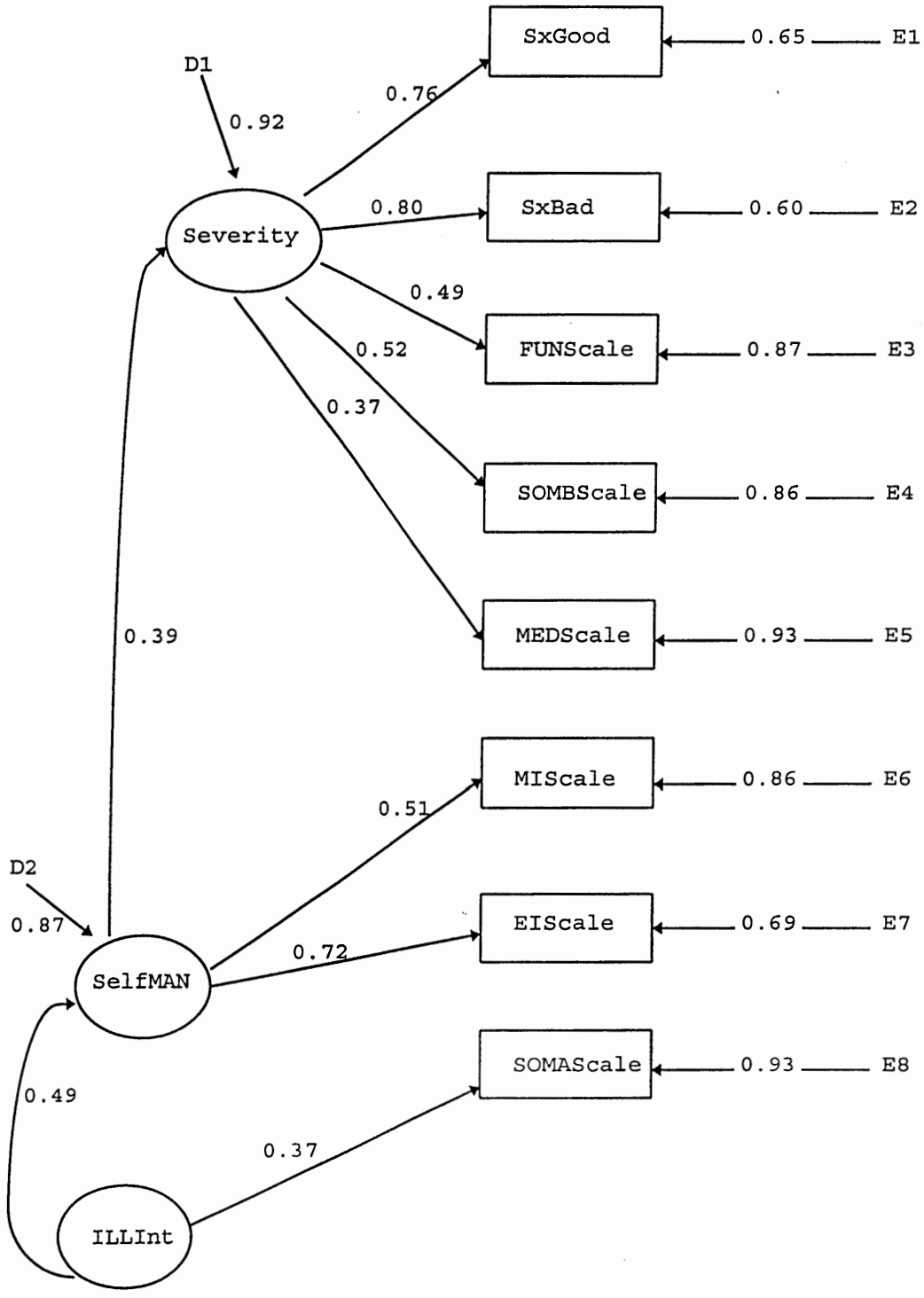
MEDICATION MANAGEMENT INTENSITY SCALE

ITEM		Percentage	Mean	Std.	Skewness	Kurtosis
48. Please list all the medicines you take for your asthma, please include when you take them and how much (if you need help with this please ask the doctor or nurse).						
MDI B2 agonist			3.251	1.832	-0.445	-0.689
Code: 0	None	15.8				
1	1 puff per day	2.9				
2	2 puffs per day	10.8				
3	3-4 puffs per day	18.6				
4	5-6 puffs per day	27.5				
5	7-8 puffs per day	13.7				
6	>8 puffs per day	10.7				
Nebulized B2 agonist			0.719	1.341	1.696	1.345
Code: 0	None	71.9				
1	<2/week	8.9				
2	3-4/week	5.4				
3	5-7/week	2.9				
4	>7/week	10.9				
Oral glucocorticoid			0.842	0.967	0.321	-1.866
Code: 0	None	55.7				
1	Part of week	4.4				
2	All of week	39.9				

		Percentage	Mean	Std.	Skewness	Kurtosis
Inhaled B2 (Long-acting) i.e. Serevent			0.837	1.327	0.983	-1.006
Code: 0	None	70.9				
1	1 puff per day	0.5				
2	2 puffs per day	2.5				
3	<2 puffs per day	26.1				
Theophylline			0.522	0.925	1.472	1.036
Code: 0	None	73.9				
1	QD	2.9				
2	BID	21.2				
3	TID	1.0				
X	Don't know	0.9				
Daily use of inhaled steroids			1.759	1.423	0.101	-1.258
Code: 0	None	30.5				
1	0-500 mg/day	9.4				
2	501-1000 mg/day	28.6				
3	1001-2000 mg/day	16.7				
4	>2000 mg/day	14.8				

APPENDIX G

Measurement Models
Goodness-of-Fit Indices


SxGood
0.65
E1
D1
0.92
0.76
Severity
0.80
SxBad
0.60
E2
0.49
FUNScale
0.87
E3
0.52
0.37
SOMBScale
0.86
E4
MEDScale
0.93
E5
0.39
MIScale
0.86
E6
0.51
D2
0.87
EIScale
0.69
E7
0.72
SelfMAN
SOMAScale
0.93
E8
0.49
0.37
ILLInt

Model 1 (M1)

Asthma Outcome Index
Program: Model 1

```
/TITLE
Asthma Outcome Index:  Model 1
/SPECIFICATIONS
 !DATA='C:\EQS\MATRIXD2.ESS'; VARIABLES=  8; CASES=  203;
 VARIABLES=  8; CASES=  203;
 METHODS=ML;
 MATRIX=CORRELATION;
/LABELS
V1=SxGood; V2=SxBad; V3=MIScale; V4=FUNScale; V5=EIScale;
V6=SOMBScal; V7=SOMAScal; V8=MedScale;
/EQUATIONS
V1 =  + *F1  + E1;
V2 =  + *F1  + E2;
V3 =  + *F2  + E3;
V4 =  + *F1  + E4;
V5 =  + *F2  + E5;
V6 =  + *F1  + E6;
V7 =  + *F3  + E7;
V8 =  + *F1  + E8;
F1 =  + *F2  + D1;
F2 =  + *F3  + D2;
/VARIANCES
F3 = *;
E1 = *;
E2 = *;
E3 = *;
E4 = *;
E5 = *;
E6 = *;
E7 = *;
E8 = *;
D1 = *;
D2 = *;
/COVARIANCES
/LMTEST
 PROCESS=SIMULTANEOUS;
 SET=PVV,PFV,PFF,PDD,GVV,GVF,GFV,GFF,BVF,BFF;
/WTEST
 PVAL=0.05;
 PRIORITY=ZERO;
/PRINT
 digit=3;
 linesize =80;
 fit=all;
/MATRIX
      1.000
      0.627      1.000
      0.212      0.125      1.000
      0.368      0.326     -0.040      1.000
      0.231      0.229      0.372      0.130      1.000
      0.348      0.426     -0.111      0.426      0.103      1.000
      0.034      0.099      0.121      0.204      0.044      0.229      1.000
      0.238      0.307      0.186      0.295      0.165      0.115      0.038
      1.000
```

MAXIMUM LIKELIHOOD SOLUTION (NORMAL DISTRIBUTION THEORY)

GOODNESS OF FIT SUMMARY: MODEL 1

INDEPENDENCE MODEL CHI-SQUARE = 319.486 ON 28 DEGREES OF FREEDOM

INDEPENDENCE AIC = 263.48570 INDEPENDENCE CAIC = 142.71593
MODEL AIC = 39.01322 MODEL CAIC = -25.68487

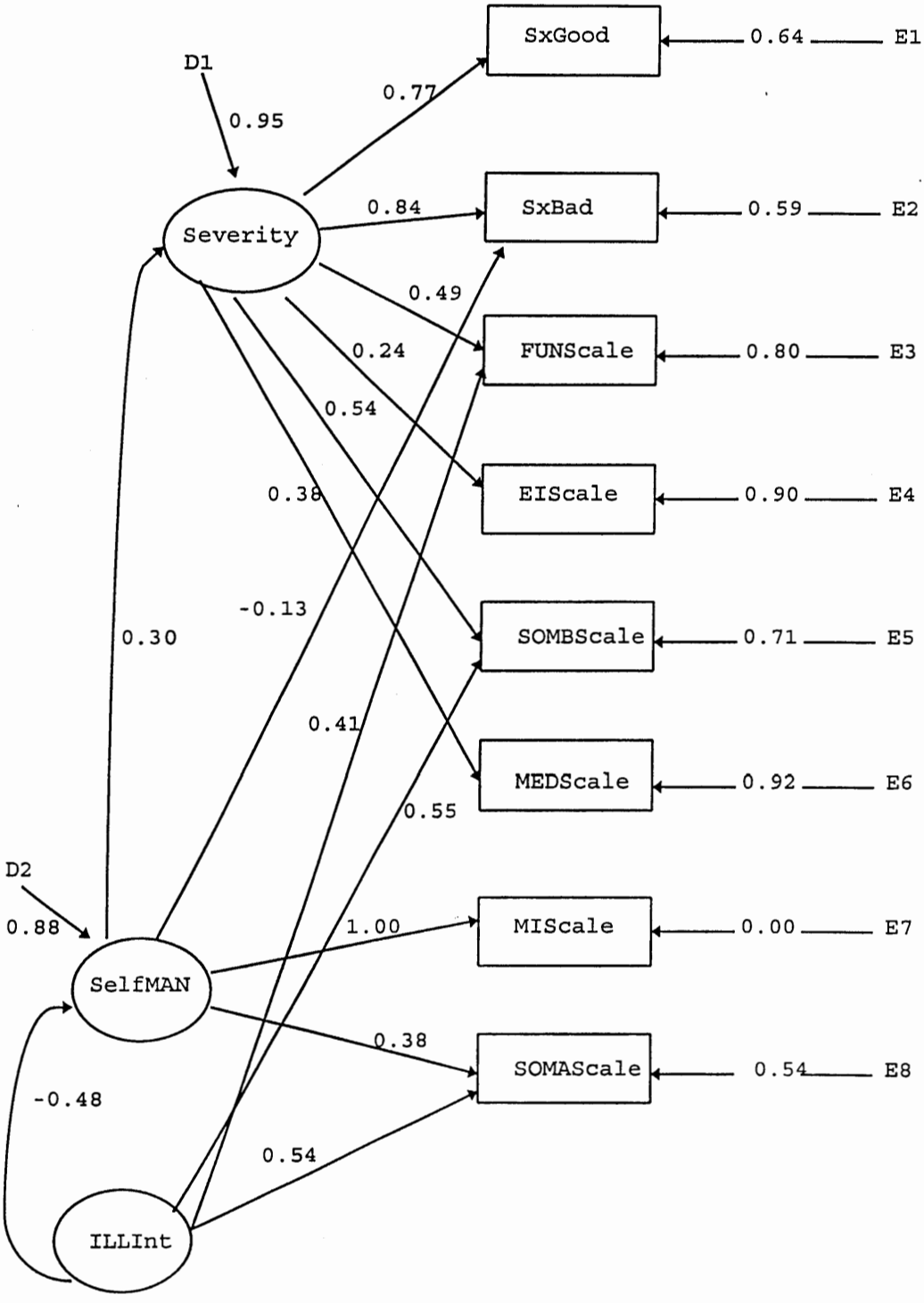
CHI-SQUARE = 69.013 BASED ON 15 DEGREES OF FREEDOM
PROBABILITY VALUE FOR THE CHI-SQUARE STATISTIC IS LESS THAN 0.001
THE NORMAL THEORY RLS CHI-SQUARE FOR THIS ML SOLUTION IS 66.136.

BENTLER-BONETT NORMED	FIT INDEX=	0.784
BENTLER-BONETT NONNORMED	FIT INDEX=	0.654
COMPARATIVE FIT INDEX (CFI)	=	0.815
BOLLEN (IFI)	FIT INDEX=	0.823
McDonald (MFI)	FIT INDEX=	0.875
LISREL GFI	FIT INDEX=	0.924
LISREL AGFI	FIT INDEX=	0.818
ROOT MEAN SQUARED RESIDUAL (RMR)	=	0.080
STANDARDIZED RMR	=	0.080
ROOT MEAN SQ. ERROR OF APP.(RMSEA)	=	0.134
90% CONFIDENCE INTERVAL OF RMSEA	(	0.102, 0.166)

MAXIMUM LIKELIHOOD SOLUTION (NORMAL DISTRIBUTION THEORY)

STANDARDIZED SOLUTION:

```
SXGOOD  =V1  =   .760*F1    + .650 E1
SXBAD   =V2  =   .803*F1    + .596 E2
MISCALE =V3  =   .511*F2    + .860 E3
FUNSCALE=V4  =   .489*F1    + .872 E4
EISCALE =V5  =   .720*F2    + .694 E5
SOMBSCAL=V6  =   .515*F1    + .857 E6
SOMASCAL=V7  =   .265*F3    + .964 E7
MEDSCALE=V8  =   .369*F1    + .929 E8
   F1    =F1  =   .388*F2    + .922 D1
   F2    =F2  =   .486*F3    + .874 D2
```


SxGood
0.64
E1
D1
0.95
0.77
Severity
0.84
SxBad
0.59
E2
0.49
0.24
FUNScale
0.80
E3
0.54
0.38
EIScale
0.90
E4
-0.13
0.30
SOMBScale
0.71
E5
0.41
MEDScale
0.92
E6
0.55
D2
0.88
1.00
MIScale
0.00
E7
SelfMAN
0.38
SOMAScale
0.54
E8
-0.48
0.54
ILLInt

Model 2 (M2)

```
Asthma Outcome Index
PROGRAM:  Model 2

 1  /TITLE
 2  Asthma Outcome Index: Model 4 (Non-significant at .05)
 3  /SPECIFICATIONS
 4   !DATA='C:\EQS\MATRIXD2.ESS'; VARIABLES=  8; CASES=  203;
 5   VARIABLES=  8; CASES=  203;
 6   METHODS=ML;
 7   MATRIX=CORRELATION;
 8  /LABELS
 9  V1=SxGood; V2=SxBad; V3=MIScale; V4=FUNScale; V5=EIScale;
10  V6=SOMBScal; V7=SOMAScal; V8=MedScale;
11  /EQUATIONS
12  V1 =   + *F1   + E1;
13  V2 =   + *F1   + *F2   + E2;
14  V3 =   + *F2   + E3;
15  V4 =   + *F1   + *F3   + E4;
16  V5 =   + *F1   + *F2   + E5;
17  V6 =   + *F1   + *F3   + E6;
18  V7 =   + *F2   + *F3   + E7;
19  V8 =   + *F1   + E8;
20  F1 =   + *F2   + D1;
21  F2 =   + *F3   + D2;
22  /VARIANCES
23  F3 = *;
24  E1 = *;
25  E2 = *;
26  E3 = *;
27  E4 = *;
28  E5 = *;
29  E6 = *;
30  E7 = *;
31  E8 = *;
32  D1 = 1;
33  D2 = 1;
34  /COVARIANCES
35  /LMTEST
36   PROCESS=SIMULTANEOUS;
37   SET=PVV,PFV,PFF,PDD,GVV,GVF,GFV,GFF,BVF,BFF;
38  /WTEST
39   PVAL=0.05;
40   PRIORITY=ZERO;
41  /PRINT
42   digit=3;
43   linesize =80;
44   fit=all;
45  /MATRIX
46        1.000
47        0.627      1.000
48        0.212      0.125      1.000
49        0.368      0.326     -0.040      1.000
50        0.231      0.229      0.372      0.130      1.000
51        0.348      0.426     -0.111      0.426      0.103      1.000
52        0.034      0.099      0.121      0.204      0.044      0.229      1.000
53        0.238      0.307      0.186      0.295      0.165      0.115      0.038
54        1.000
```

MAXIMUM LIKELIHOOD SOLUTION (NORMAL DISTRIBUTION THEORY)

GOODNESS OF FIT SUMMARY: Model 4

INDEPENDENCE MODEL CHI-SQUARE = 319.486 ON 28 DEGREES OF FREEDOM

INDEPENDENCE AIC = 263.48570 INDEPENDENCE CAIC = 142.71593
MODEL AIC = -4.10091 MODEL CAIC = -55.85938

CHI-SQUARE = 19.899 BASED ON 12 DEGREES OF FREEDOM
PROBABILITY VALUE FOR THE CHI-SQUARE STATISTIC IS 0.06902
THE NORMAL THEORY RLS CHI-SQUARE FOR THIS ML SOLUTION IS 18.507.

BENTLER-BONETT NORMED	FIT INDEX=	0.938
BENTLER-BONETT NONNORMED	FIT INDEX=	0.937
COMPARATIVE FIT INDEX (CFI)	=	0.973
BOLLEN (IFI)	FIT INDEX=	0.974
McDonald (MFI)	FIT INDEX=	0.981
LISREL GFI	FIT INDEX=	0.978
LISREL AGFI	FIT INDEX=	0.933
ROOT MEAN SQUARED RESIDUAL (RMR)	=	0.036
STANDARDIZED RMR	=	0.036
ROOT MEAN SQ. ERROR OF APP.(RMSEA)	=	0.057
90% CONFIDENCE INTERVAL OF RMSEA (	0.000,	0.100)

MAXIMUM LIKELIHOOD SOLUTION (NORMAL DISTRIBUTION THEORY)

STANDARDIZED SOLUTION:

```
SXGOOD  =V1  =   .768*F1    + .641 E1
SXBAD   =V2  =   .839*F1    +-.126*F2    + .587 E2
MISCALE =V3  = 1.000*F2     + .000 E3
FUNSCALE=V4  =   .494*F1    + .414*F3    + .802 E4
EISCALE =V5  =   .244*F1    + .299*F2    + .899 E5
SOMBSCAL=V6  =   .537*F1    + .547*F3    + .705 E6
SOMASCAL=V7  =   .383*F2    + .542*F3    + .872 E7
MEDSCALE=V8  =   .381*F1    + .924 E8
   F1    =F1  =   .300*F2    + .954 D1
   F2    =F2  =  -.484*F3    + .875 D2
```