FACTORS RELATED TO TREATMENT REGIMEN ADHERENCE IN CHILDREN
AND ADOLESCENTS WITH ASTHMA

DISSERTATION

Presented in Partial Fulfillment of the Requirements for
the Degree Doctor of Philosophy in the Graduate School of
The Ohio State University

By

Kellie Michele McCants, M.A.

****

The Ohio State University

2003

Dissertation Committee:

Professor Thomas Linscheid, Advisor Approved by
Professor Steven Beck
Professor Michael Walker

Advisor

Psychology Graduate Program
Treatment regimen adherence is a well-documented problem in pediatric psychology. The literature is replete with studies indicating that adherence in pediatric chronic illnesses is significantly correlated with several family- and child-related psychosocial variables. The current work proposed and tested a model of treatment regimen adherence (as defined as prescription refill rate with physiological outcome as a covariate) for children and adolescents with asthma. The results suggest that although none of the proposed model variables (attention deficit-related behavior, secondary gain, family life stress, and child-reported illness attitudes) is a significant predictor of adherence, secondary gain does moderate the relationship between asthma severity and adherence (with peak flow as a
covariate). More specifically, a significant positive correlation between severity and adherence exists only when secondary gain is low; otherwise, the correlation is non-significant. The optimal linear combination of participant age, secondary gain, child-reported illness attitudes, family stress, and attention-related behavior problems is not a significant predictor of prescription refill rate when physiological outcome is covaried from refill rate. This finding is consistent with the notion that outcome is in some way related to adherence and should not be considered a nuisance or control variable.
Dedicated to my uncle George Claverie
ACKNOWLEDGMENTS

First and foremost, I offer praise and thanksgiving to my Lord and Savior, Jesus Christ, for His saving power. Lord, You have shown me over the past 30 years that there is nothing too hard for us to face together. You have picked me up every time I have fallen down, even when I could not see my way to the next victory. Thank you for every struggle, every trial, and every victory You have placed in my path. I am so grateful to know that You are the source of my strength and the strength of my life.

I wish to thank my advisor, Dr. Thomas Linscheid, for his assistance through this process. I wish to express my gratitude to Dr. Steven Beck his mentoring and thoughtful remarks on this and my comprehensive exam project.
I wish to express special thanks and undying gratitude to Dr. Michael Walker who has functioned as a mentor, a copy editor, a career counselor, and a true source of inspiration throughout my graduate career. I can honestly say that I would not have been able to make it through this process without Dr. Walker’s guidance.

Special thanks to the Pulmonary and Allergy and Developmental and Behavioral Pediatrics staff at the University of Maryland Medical Center, Dr. Mary Beth Bollinger, and Dr. Vicki Tepper for their support, without which this project would have been impossible to complete. Special thanks to Diane Mollinaro for keeping me up-to-date with schedules for clinic.

To Dr. Chad Nelson, Dr. Steven Band, Dr. Erik Scott, and Dr. Judith J. Grados and the staff at Mount Washington Pediatric Hospital for being supportive of my academic pursuits, I am truly grateful and honored to work in the company of such wonderful people.

I also owe a special debt of gratitude to Dr. Freeman Hrabowski, Mrs. Earnestine Baker, Mr. LaMont Toliver, and the Meyerhoff Scholarship Program staff who helped to sustain me during my undergraduate years and helped to
kindle my hunger for knowledge even when “hungry” was not the “in” thing to be.

Thank you to Dr. Alicia Diaz who was my eyes, ears, and feet in Columbus when I could not be there myself. Alicia, I am truly indebted to you for all that you have done for (and with) me over the years. Special thank you to Sean Sullivan (soon-to-be Dr. Sean Sullivan) who “talked me down out of a tree” on more than one occasion.

To Cynthia and Harrison Joseph I am grateful for your listening to my many lamentations over the years without complaining or turning me away. I am thankful for your support, your friendship, and your prayers. And I am so overjoyed that one of your dreams has been realized in your beautiful Sydney.

To my church family at The Community of Holy Rosary and St. John in Columbus, Ohio for keeping me grounded and for praying me through my situations time after time after time, I am overwhelmingly grateful.

To Dr. Karla Paylor, Dr. Jennifer Brown, Kay Washington, Marc “Louie” Taylor, Sonya Johnson-Branch, Shreya Patel-Hessler, Gwyn Gerner, Nicole Glick, Kendel Wylie-Pugh, Lynda Gibson, and Keisha Hawthorne, thank you for lending your support whenever I needed it.
To Stacey and Karl Nelson, Susie McNeill, Mary Klausing, Nancy Vaughn, Cindy Bivins, and Monique Stubbs-Holliday, thank you for being my second family. You have all supported, comforted, and encouraged me in ways that you will never truly understand. Thank you for keeping me in your prayers and for keeping me mindful of the power of prayer.

To Garrett Cordell for being my best friend for more than half of my life. You have stood by me through every up, down, heartache, and disappointment over the past 15+ years. I am grateful to God every day for your support, love, selflessness, and encouragement throughout this process and through every challenge in my life since 1986. Thank you for listening to me, for giving me a “swift kick in the pants” on occasion, for wiping my tears, for always “coming to the rescue,” and for loving me no matter what.

To my grandmother, Rebecca McCants, thank you for giving me the gift of my family history and the inspiration to make a better life for myself. You will never know how you have inspired me.

To Marie Childs and Sally Claverie, my aunts, who prayed for me daily and provided words of support or a shoulder to cry on whenever I needed one. Thank you for
being “stand-in godparents” after Uncle Toby was taken Home.

To my brother Corey and to my parents Robert and Isabelle McCants, thank you for your love and support throughout this process. Thank you for showing me the importance of discipline, goal-setting, and perseverance. There are not enough words to express my gratitude for how much you’ve done and how much you mean to me.

Finally, I am so immensely grateful to each and every person who has supported and prayed for me throughout this process. I truly believe that the successful completion of my graduate work is not my victory, but our dream coming to fruition. Each and every one of you is a shareholder in this project.
VITA

August 13, 1972  Born, Washington, DC

1995     B.S., Interdisciplinary Studies
         University of Maryland
         Baltimore County

1996 – 1999   Graduate Teaching Associate
          Department of Psychology
          The Ohio State University

1997     M.A., Psychology – Clinical
         The Ohio State University

2000     Pre-Doctoral Intern
         University of Maryland
         School of Medicine

2001 – present   Pediatric Psychology Fellow
          Mt. Washington Pediatric Hospital

FIELD OF STUDY

Major Field: Psychology

x
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>ii</td>
</tr>
<tr>
<td>Dedication</td>
<td>iv</td>
</tr>
<tr>
<td>Acknowledgments</td>
<td>v</td>
</tr>
<tr>
<td>Vita</td>
<td>x</td>
</tr>
<tr>
<td>List of Tables</td>
<td>xiii</td>
</tr>
<tr>
<td>List of Figures</td>
<td>xv</td>
</tr>
<tr>
<td>Chapters:</td>
<td></td>
</tr>
<tr>
<td>1. Introduction</td>
<td>1</td>
</tr>
<tr>
<td>2. Methods</td>
<td>56</td>
</tr>
<tr>
<td>3. Results</td>
<td>67</td>
</tr>
<tr>
<td>4. Discussion</td>
<td>88</td>
</tr>
<tr>
<td>References</td>
<td>101</td>
</tr>
<tr>
<td>Appendix A: Children’s Attitude Toward Illness</td>
<td></td>
</tr>
<tr>
<td>Scale</td>
<td>109</td>
</tr>
</tbody>
</table>
Appendix B: Illness Behavior Encouragement Scale, Child Version ................................................................. 113
Appendix C: Illness Behavior Encouragement Scale Parent Version .............................................................. 116
Appendix D: Family Inventory of Life Events and Changes ............................................................................ 119
Appendix E: ADHD Rating Scale .................................................................................................................... 122
Appendix F: Research Consent Form .............................................................................................................. 124
Appendix G: Medical/Pharmacy Research Consent Form ................................................................................ 129
Appendix H: Adolescent Assent Form ............................................................................................................ 132
# LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Summary of Major Variable Means and Standard Deviations</td>
<td>71</td>
</tr>
<tr>
<td>3.2 Summary of FILE Scores by Age and Stress Category</td>
<td>72</td>
</tr>
<tr>
<td>3.3 Correlation Matrix for Major Study Variables</td>
<td>73</td>
</tr>
<tr>
<td>3.4 Simple and Semi-Partial Correlations for Predictors Related to Refill Rate</td>
<td>75</td>
</tr>
<tr>
<td>3.5 Summary of Hierarchical Regression for ADHD-Related Behavior, Age, and Prescription Refill Rate</td>
<td>77</td>
</tr>
</tbody>
</table>
3.6 Summary of Hierarchical Regression Analysis for Secondary Gain Difference, Severity, and Prescription Refill Rate ................................................................. 81

3.7 Summary of Hierarchical Regression Analysis for Illness-Related Attitudes, Secondary Gain Difference, and Refill Adherence .............................................. 83

3.8 Summary of Hierarchical Regression Analysis for the Full Adherence Model ................................................................. 85
## LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Adherence Model: Stage</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>1</td>
<td>40</td>
</tr>
<tr>
<td>1.2</td>
<td>2</td>
<td>41</td>
</tr>
<tr>
<td>1.3</td>
<td>3</td>
<td>42</td>
</tr>
<tr>
<td>1.4</td>
<td>4</td>
<td>44</td>
</tr>
</tbody>
</table>
CHAPTER 1:

INTRODUCTION

Adherence to medication/treatment regimens is a formidable medical issue that has recently become one of the most studied topics in pediatric and health psychology (Taylor, 1995). Lemanek (1990), in a review of the treatment adherence literature in pediatric asthma, suggested that across disorders, failure to comply with prescribed medication regimens is the health behavior about which medical and mental health professionals understand very little.

Rapoff (1998) suggested that nonadherence is a grave issue in pediatric chronic illnesses, and Lemanek (1990) reported that nearly half of all patients regardless of age (46%) prescribed long-term therapies are nonadherent. Litt and Cuskey (1980) estimated that adherence rates are similar for pediatric populations. Lemanek further
suggested that nonadherence to medication regimens in pediatric populations is about 50%. Sadly, our accounts of nonadherence rates may be largely underestimated as the data are based on reports from those willing to participate in studies and those undergoing treatment geared toward improving previously identified adherence problems (Epstein & Cluss, 1982; La Greca, 1990).

In chronically ill patients, regardless of age, the measurable effects of nonadherence are numerous. They include interference with treatment efficacy, for example, symptom exacerbation or lack of response to treatment. This is an especially grave problem in patients with human immunodeficiency (HIV) wherein nonadherence renders certain antiretroviral drugs ineffective. Nonadherence frequently results in enormous health care time and financial expenditures, and for some patients, death (Lemanek, 1990; VanSciver, D’Angelo, Rappaport, & Woolf, 1995; Rapoff, 1998). In pediatric populations nonadherence is potentially more deleterious because chronic illnesses diagnosed in childhood manifest themselves over a longer segment of the lifespan (i.e., over the individual’s childhood, adolescence, and adult years). This ultimately presents more opportunities for nonadherence, often leading
to poor treatment efficacy, unnecessary financial expenditure, and greatly increased risk of premature death. Despite the small number of children and adolescents affected by chronic physical illnesses (Rapoff, 1998), the potential benefits of studying treatment adherence can not be ignored. Understanding variables related to adherence and its effects on health outcomes can greatly assist professionals in implementing regimens aimed at increasing a child’s physiological functioning thereby potentially increasing that child’s lifespan.

Treatment Adherence Versus Treatment Compliance

Before the reader can gain an in-depth understanding of adherence it is crucial that he or she understand the difference between “adherence” and “compliance.” These terms are often used interchangeably in the literature and in clinical practice (La Greca & Schuman, 1995).

Compliance is an older and arguably more widely accepted term that refers to a patient’s heeding medical advice, typically with respect to pharmacological treatments. La Greca and Schuman (1995) suggested that the definition of compliance implies that a patient’s conduct of health-related behaviors can be compared to some predetermined standard. Use of the term “adherence” in
place of “compliance” represents an implied acknowledgment that patient behaviors are not being compared to a preset standard.

Voyles and Menendez (1983) discussed the differences between compliance and adherence, conceptualizing the two entities as parts of a continuum that describes the nature of the relationship between a patient and his/her health care provider. In Voyles and Menendez’s model, compliance represents one end of the continuum and therapeutic alliance the other. Therapeutic alliance describes the optimal relationship between the physician and patient, implying a partnership between the two. This alliance is a key factor in the treatment of chronic illness, where contact with health care providers and “mutual decision making” (p. 355) are ongoing (Gavin et al., 1999). Compliance, the less desirable anchor of the continuum, implies that the health care provider may simply direct the patient to follow a prescribed regimen without the patient’s input. Adherence, suggested the authors, falls in the middle of this continuum. Jay (1997) also supported the notion that adherence represents a doctor-patient partnership that works to improve therapeutic success. The literature suggests that adherence is more desirable than
compliance. From this point on, therefore, the term “adherence” will be used in place of “compliance” to reflect the patient’s appropriate use of treatment regimens.

Measuring Adherence

LaGreca (1990) suggested that problems with adherence tend to vary with the complexity of the disorder and the treatment regimen, the age of the patient, and the method used to assess adherence. An issue central to the measurement of adherence is operationalization of the construct.

LaGreca and Schuman (1995) and Cromer and Tarnowski (1989) implied that it is quite common for researchers and medical professionals to dichotomize patients’ adherence behaviors into “good” versus “poor” or “adherent” versus “nonadherent.” In addition to the loss of information that results from the unnecessary truncation of adherence, dichotomization of adherence is problematic because it demands that the researcher or medical professional apply cutoff scores that may not make practical sense. For most disorders there is no standard that constitutes sufficient adherence. La Greca and Schuman and Cromer and Tarnowski, therefore, advised researchers to abstain from using...
dichotomized classification systems. This advice, however, has not been heeded. Categorical systems are so engrained in the adherence research culture and the field of psychology that they will likely live on despite their methodological pitfalls.

LaGreca and Schuman and Cromer and Tarnowski agreed that the best alternative to using dichotomized classification systems is the use of percentage definitions (ratios of adherent behaviors). Cromer and Tarnowski (1989) suggested that percentage definitions are the most direct and useful means of explaining adherence. La Greca and Schuman (1995) supported the use of percentage definitions to quantify adherence.

LaGreca and Schuman (1995), Lemanek (1990), Cromer and Tarnowski (1989), and Epstein and Cluss (1982), among others, suggested that a variety of methods are available for assessing the construct of treatment adherence. These methods fall into two categories: direct and indirect assessments.

Direct methods of assessment include biochemical assays of blood, urine, or physiological functioning. Depending on the disorder in question, one or more of these direct methods may be used. In individuals with asthma,
biochemical assays assess levels of theophylline-based compounds (Lemanek, 1990); theophylline was at one time one of the more frequently used pharmacotherapeutic agents for asthmatics. For individuals with insulin-dependent diabetes mellitus (IDDM), direct assessment is typically the measurement of glycosylated hemoglobin (GHB), an index of the diabetic patient’s metabolic control. In other disorders, e.g., juvenile rheumatoid arthritis (JRA) or seizures, levels of various drugs (e.g., anticonvulsants, anti-inflammatory drugs) in the blood are direct assessments of adherence.

It was once thought that blood assays and other physiological measures were the best means of assessing adherence. Recently, however, this notion has met with criticism in the pediatric psychology literature. Cromer and Tarnowski (1989) suggested that blood and biochemical assays can be problematic when an individual has medical conditions, for example, food or drug interactions or metabolic difficulties that may impede the absorption of the target drug into the bloodstream. Thus, it is entirely possible, although somewhat unlikely, that a patient may take medication as prescribed but may not demonstrate blood levels that are consistent with medical standards.
Hentinen and Kyngas (1996) presented another criticism of the use of direct assays in measuring adherence. Blood and biochemical assays, they proposed, are not measures of adherence behavior. Assays, instead, are outcome assessments. Although health researchers are ultimately interested in the outcome produced by adherence-related behaviors, they investigate the process of adherence in order to develop a means of intervention on these behaviors. Health researchers, and especially psychologists, are more equipped to assist a patient in changing behaviors rather than directly affecting blood test results.

Hentinen and Kyngas and others recommend the use of indirect methods of assessment, as these measures are the only true way to understand the process of adherence rather than the outcome. Several indirect methods of assessing adherence exist. One of the more commonly utilized indirect methods in the health psychology literature is self-report; in the pediatric psychology literature this includes parent-report. Many psychometrically sound self-report instruments have been developed over the past several of decades. While these instruments are far less expensive to administer and to interpret than are blood
assays, self-report measures are not used without a price. Child or adolescent self-report and parent-report data are notoriously susceptible to socially desirable responding. For this reason, the use of self-report data alone as criterion variables in adherence studies may lead to inflated estimates of adherence (Daviss et al., 1995), largely due to the inherent confound of adherence self-report with illness-related knowledge. That is, when the researcher asks the child or his or her parent to report on adherence, the patient or parent may respond not with accurate information about his or her personal experience but with accounts of what has been learned about the regimen.

An alternate indirect method of measuring adherence which should be less influenced by socially desirable responding is the use of physicians’ or nurses’ ratings. La Greca and Schuman (1995) suggest that the use of medical professionals’ ratings is an improvement over the use of self-report data. Despite the alleged objectivity of professionals’ ratings, these data are still more subjective in nature than should be acceptable because they are person-reported ratings that are not based on an established quantitative scale. This writer believes that
the use of physicians’ ratings as the sole measure of adherence can result in the researcher’s inadvertent dismissal of relevant behaviors that occur outside of the medical office. Another complication with physicians’ ratings is that the physician’s assessment of the child’s or parent’s adherence is necessarily confounded with physiological outcome (M. Bollinger, personal communication, September 30, 2002). That is, the physician’s ideas about a patient’s adherence are affected by how healthy the patient appears to be or how well-controlled his or her illness-related symptoms are.

Recording pill counts or counting other disposable or consumable medical supplies is another means of indirect adherence assessment that, unlike physicians’ rating, is unaffected by the patient’s presentation at the clinic visit. Pill counts are thought to yield a more global account of adherence behavior. This method is not, however, a perfect means of assessing adherence. The greatest barrier to the use of this method of assessment is that patients are likely to dispose of pills/supplies to appear more adherent if they are aware that their supplies are being evaluated (Cromer & Tarnowski, 1989). Patients may also share medication with friends and family members
or forget to bring their medications with them to the assessment. These facts suggest that overestimates of adherence may result from the sole use of pill counts as criterion variables.

Another method of assessing adherence that is related to pill counts but seemingly unaffected by participants’ socially desirable responding is assessment of pharmacy records. To evaluate adherence to prescribed medications the researcher reviews a patient’s refill rate over a specified interval, for example, six months or one year. Although using this method of adherence assessment can be logistically difficult because some patients utilize multiple pharmacies to refill their prescriptions, refill rate assessment yields an indirect measure that likely approximates the pattern with which the child takes his or her medications. This method is likely a good estimate of adherence because most patients are not apt to refill prescriptions until they need to do so. If prescription refill rates are gleaned, for example, from six months of pharmacy records covering prescriptions filled before the patient’s recruitment into a study, patients and their parents are unable to intentionally alter their refill histories by changing their current behavior.
Another approach to assessing adherence that continues to gain popularity is recording appointment-keeping. Researchers are examining the frequency with which the patient attends, reschedules, and/or cancels appointments in their assessments of adherence. Finney, Lemanek, Brophy, and Cataldo (1990) indicated that failure to adhere to scheduled appointments is a grave problem. By their estimate, 20 to 50% of chronically ill children and adolescents miss scheduled appointments in pediatric health care settings. The use of appointment-keeping data as the lone measure of adherence, however, is not without its complications. Although attending scheduled appointments is certainly a piece of the total picture of adherence, measuring appointment-keeping is not a substitute for measuring adherence to other crucial components of the prescribed treatment regimen, such as medication. Failure to attend scheduled appointments, however, is likely to correlate with how the patient engages in other prescribed behaviors outside of the medical clinic (Finney et al., 1990).

As a final note on understanding the construct of adherence, it is important to consider the combination of multidimensional self-report measures, medical
professionals’ ratings, biochemical assays, and appointment-keeping behavior into a single index of nonadherence. Law and King (1993) suggested the use of multiple indicators of adherence, assuming that good estimates of adherence included information obtained from parents and from professionals caring for the patient. Multidimensional assessment allows researchers to gain a more accurate measure of adherence by canceling out the effects of method, or unwanted, variance (Glasgow et al., 1986). Utilization of multiple measures also permits scientists to investigate the associations among multiple modes of assessment in much the same way that Campbell and Fiske (1959) did in their multitrait-multimethod matrix. To date, however, no one has established an optimal method of combining the various adherence indicators into a solitary adherence index.

Cromer and Tarnowski (1989) also discussed the use of multidimensional assessment. They were more critical of this method than were Law and King. Cromer and Tarnowski suggested that multidimensional assessment evidences weaker statistical properties and is restricted by variation in methods across studies. In their opinion percentage definitions for individual aspects of adherence should be
utilized in research to guarantee that the importance of each behavior can be appreciated. LaGreca and Schuman (1995) support the assertions of Cromer and Tarnowski, suggesting that combining multiple adherence indicators may “mask the significance of individual adherence behaviors” (p. 57).

There are many issues that must be considered in the selection of an appropriate index of adherence. Most importantly, it appears that each index of adherence evidences some flaw or methodological pitfall. Self-report and physicians’ ratings are often too subjective. Pill counts can often be influenced by the patient’s/parent’s manipulation of the medication prior to an assessment. Appointment-keeping ignores whether the patient is taking medications or following other prescribed changes in lifestyle (e.g., dietary guidelines). Multiple measures also have pitfalls associated with them, not the least of which is the issue of combining measures into a usable unitary quantitative variable to be included in statistical analyses.

In some chronic illness conditions adherence is simple to measure as it is highly correlated with physiological outcome. For example, physicians measure serum hemoglobin
A1C (HbA1C) levels in diabetic patients to obtain a proxy measure of insulin adherence because when HbA1C levels are within an appropriate range, the physician can assume that the patient has taken insulin as prescribed. In individuals taking anticoagulant or anticonvulsant medications, blood levels of the medications in question are well correlated with adherence. In other disorders, such as asthma, blood assays are not always effective in informing the professional about the process of adherence or are not routinely used to assess the effectiveness of a particular medication.

Under conditions in which a physician or researcher can not assess adherence using an outcome measure as a proxy, it is necessary to find an optimal method for understanding treatment regimen adherence. The path to finding this “optimal method” might begin with the selection of the least biased single measure of adherence and building from there. Based on the literature reviewed earlier in this section, it appears that pharmacy records show the greatest promise of providing an appropriate and unbiased measure of adherence, as they are not marred by socially desirable responding and can not be influenced retrospectively by the patient.
Physiological outcome, while not a true measure of adherence, may be a variable that can be “combined” with pharmacy data to gain a greater understanding of adherence. A reasonable assumption regarding the relationship between physiological outcome and adherence is that the relationship is bidirectional as poor adherence may predict poor outcome, and poor outcome may encourage adherence. If adherence and outcome influence each other, it might make sense to assess adherence by removing part of adherence that is predicted by outcome. Thus, adherence, as measured by pharmacy data with outcome removed, could be conceptualized as the how an individual follows a prescribed regimen regardless of symptom severity. This method will be utilized to assess adherence in the current study, i.e., adherence will be conceptualized as prescription refill rate with physiological outcome (in this case peak expiratory flow) used as a statistical covariate.

Adherence and Health Outcomes

A recent study by Patterson, Budd, Goetz, and Warwick (1993) underscored the facilitating role of adherence on health outcomes. If the purpose of pediatric psychology is to address "the full range of physical and mental
development, health, and illness issues affecting children, adolescents, and families...” (Roberts, LaGreca, & Harper, 1988, p.2), it is important for pediatric psychologists continue to study adherence-related behaviors. If risk or protective factors related to adherence behaviors can be identified, it is crucial for health researchers to study these variables. The examination of such variables may lead to the development of new interventions for individuals with adherence problems. To that end, the remainder of this chapter will review the relevant pediatric psychology literature regarding patient- and family-related factors associated with adherence to treatment regimens in children and adolescents. The overarching goal of the current work is to incorporate these variables into a model for predicting treatment regimen adherence in pediatric chronic illnesses.

Efforts to study adherence in children and adolescents with chronic illnesses have generated a long list of variables that may be related to pediatric treatment regimens adherence. These efforts are also responsible for a great deal of confusion that surrounds the study of the well-documented but still incompletely understood phenomenon.
It is important to understand that among the plethora of studies examining adherence-related behaviors, many studies have investigated adherence to short-term regimens, for example, short-term antibiotic treatment. Others document adherence as related to non-chronic problems such as condom or contact lens use. Although non-chronic problems are important and worthy of more detailed examination, the issue of regimen adherence is a considerably greater problem for individuals with chronic illnesses. As such, the literature reviewed in preparation for model development in the current study will focus on family- and patient-related factors in chronic illness conditions. It is important to note that the medications prescribed to the participants in the reviewed studies are most often prophylactic (preventive) in nature.

This work will ultimately focus on adherence in children and adolescents with asthma. The issue of long-term versus short-term medication use in this population is an important one to consider. In this writer’s experience, there are many individuals with asthma who are prescribed medications, such as albuterol, on an “as needed,” or PRN basis. Others are prescribed prophylactics medications, such as Singulair or Advair. Still others are prescribed
both PRN and prophylactic medications. For the purposes of this study, prophylactic medications will be studied because it is possible to examine the patterns with which these individuals take their medications, as compared to the prescribed regimens. It is impossible to track adherence rates for individuals taking only PRN medications because their medications are not prescribed to be taken at regular intervals.

Family-Related Variables Associated with Adherence

The influence of a child’s family environment on his or her chronic illness was acknowledged by Peshkin in the 1930s (1930, as cited in Campbell, 1993). Although Peshkin may not have been the first researcher to suggest that chronic illness in children is affected by family variables, his work illustrates early ideas about family variables and interventions used to improve children’s health outcomes. Peshkin suggested that in families with asthmatic children, the family environment provoked the child’s attacks. As a result, he recommended that asthmatic children be removed from their families, a process he termed “parentectomy.”

The study of family variables and their effect on chronic illness has evolved since Peshkin’s work in the
1930s. Eaton et al. (1992) suggested that family processes, in particular, positive family interactions, may serve to improve health outcomes through the facilitation of adherence behaviors. Research in this area within the past 15 years has investigated the influence of family environment (e.g., Hanson, DeGuire, Schinkel, Henggeler, & Burghen, 1992), stress (Hanson, Henggeler, & Burghen, 1987), and coping (Reid, DuBow, Carey, & Dura, 1994) on adherence. Another growing trend in the study of adherence is the influence of this process on the family unit (Hauser et al., 1990).

An example of current efforts to understand the influence of the family on the chronic illness process is the Miller Johnson et al. (1994) examination of parent-child relationships and the management of insulin-dependent diabetes mellitus (IDDM). Using multiple indicators of adherence, Miller Johnson and her colleagues found that with higher levels of conflict present in the family, a child is at increased risk for self-reported and other-reported nonadherence and poor metabolic control. An earlier study by Martin, Miller Johnson, Kitzmann, & Emery
(1998) suggested that the family’s ability to resolve conflict can aid in management of the child’s treatment regimen.

Manne et al. (1993) undertook an examination of the role of parenting style in treatment adherence in the pediatric oncology population. Although cancer’s course can be punctuated by periods of remission, it is a chronic disorder that presents the family with difficult issues with respect to adherence. Adherence in the Manne et al. sample was measured using multiple means, including appointment-keeping, medication adherence, and maintenance of central line access and diet. Nurturing parents in the Manne et al. sample were more likely to attend scheduled appointments and to report negative reactions to treatment, such as side effects. This result supports the notion that parenting style is related to parents’ accomplishment of adherence-related behaviors. Nurturing parents and those who exhibit appropriate control over the child’s misbehavior are more likely to be adherent to the treatment regimen.

Manne et al. also suggested that the nurturing, supportive parent may be better able to encourage the child’s expression of his or her needs and is also likely
to respond to the child’s needs in a more supportive manner. This more supportive reaction to the child may translate into the performance of adherence-facilitating behaviors, such as attending scheduled clinic appointments and retrieving prescriptions in a timely manner. The researchers also suggested that nurturing parents may simply be more likely to follow through on appointments and medically-related tasks involved in the care of their children.

The final major point that comes from the Manne et al. study is that there are relationships among parenting style, family cohesion, stress, and conflict. Supportive parenting predicts family cohesion and lower levels of stress and conflict. The researchers indicated that additional research should be done to further examine the interplay of these variables and their association with treatment adherence.

Research by Van Sciver, D’Angelo, Rappaport, & Woolf (1995), drawing from multiple pediatric chronic illness populations, addressed some of the deficits in the pediatric chronic illness literature with respect to family-related variables. Van Sciver et al. explained the relationship of family stress to adherence across certain
disorders (asthma, sickle cell disease, and hemophilia) by highlighting the complexity and continuity inherent in treatment regimens. The family’s adherence, or attempts at adherence, likely exacerbate an already stressful family situation. The exacerbation may, in turn, affect a parent’s motivation or ability to perform adherence-related behaviors.

Taken together the findings of Van Sciver et al. (1995), Manne et al. (1993), Martin et al. (1998), and Miller Johnson et al. (1994) suggest that stress, conflict, parenting style, and cohesion may all be good predictors of adherence. Supportive parenting is likely a predictor of decreased conflict and greater cohesion. Lower levels of conflict and greater cohesion will likely correlate with lower levels of family stress. In less stressful situations, adherence will be more favorable.

In their 1983 article Schafer, Glasgow, McCaul, and Dreher suggested that increased family conflict and a child’s negative interactions with his or her mother were related to poor treatment adherence. A decade later, to further probe the effects of family conflict in the adherence process, Wysocki (1993) examined parent-child conflict in adolescent-parent dyads in which the adolescent
had IDDM. He found a positive relationship between family functioning and adherence and that more effective family communication is associated with better treatment regimen adherence.

Wysocki suggested a mechanism by which these family variables might work to affect adherence and the child’s adjustment to IDDM. Poor communication may lead to failure to resolve family conflicts. Manne et al. (1993) supported the notion that more effective conflict resolution is related to better adherence. It is possible that adjustment to the child’s chronic illness or to the treatment regimen (Van Sciver et al., 1995) may disrupt the family structure. From the child’s perspective this disruption may take the form of developmentally inappropriate levels of parent involvement in the child’s life. Parental overinvolvement may lead to additional conflict, communication problems, and potential confusion about who is responsible for caring for the child’s medical needs.

In summary, the literature reporting family-related predictors of treatment regimen adherence suggests that greater adherence is related to more nurturing parenting (Manne et al., 1993); lower levels of family stress and
conflict (Miller Johnson et al., 1994; Martin et al., 1998; Van Sciver et al., 1995; Wysocki, 1993). Although the majority of the research in adherence to pediatric chronic illness regimens has utilized the child and adolescent IDDM population, the results of the reviewed studies suggest that a positive family environment may optimize adherence across pediatric chronic illnesses.

Child-Related Variables Associated with Adherence

Despite the child’s reliance on a parent’s assistance in the process of adherence to treatment regimens, family-related variables are not the only ones that appear to influence adherence behaviors in children and adolescents with chronic illnesses. Of the aforementioned studies examining family-related variables, some indicate that special issues arise when the child with a chronic illness becomes an adolescent (e.g., Martin, Miller Johnson, Kitzmann, & Emery, 1998; Bennett-Murphy, Thompson, & Morris, 1997). With the onset of adolescence, the patient ideally assumes the majority of the responsibility for performing his or her own health maintenance behaviors, often without a great deal of parental supervision (Harris et al., 1999). Especially during adolescence, psychosocial variables directly related to the identified patient are
expected to influence the conduct of adherence-related behaviors. The next section of this chapter will review studies identifying patient-related variables associated with treatment regimen adherence.

Several studies have examined patient-related factors, finding clear relationships between components of coping style and the performance of adherence-related behaviors. Reid, DuBow, Carey, and Dura (1994) found approach coping, the use of cognitive or behavioral strategies directed toward a stressor, to be positively related to adherence in adolescent insulin-dependent diabetes mellitus patients. The use of avoidant coping strategies, such as internalizing or distancing, was negatively related to adherence behaviors in the Reid et al. sample.

An earlier effort by Heiby et al. (1989) found the social support aspect of approach coping to be related to adherence. Seeking support from friends and family was positively correlated with adolescent-reported adherence. The researchers also found that self-reinforcement for performing adherence behaviors was a positive correlate of adherence.

Bennett-Murphy et al. (1997) found adherence to be related to adolescent cognitive appraisals in an IDDM
sample. One such cognitive appraisal is external attributional style, that is, beliefs consistent with the notion that the patient can do little or nothing to affect the outcome of life events. Bennett-Murphy and her colleagues found adolescents endorsing external attributional style experienced greater difficulties with adherence. Adolescents reporting more external perceptions of their power to control their illness (external locus of control) were also noted to experience greater difficulty with adherence. Eaton et al. (1992) and Heiby et al. (1989) supported Bennett-Murphy and her colleagues’ finding suggesting that external locus of control is related to poorer adherence. Eaton et al. and Heiby et al. reported that internal locus of control (internal perceptions of power to control a disorder) was related to greater adherence as measured by chart review or by self-report in samples of adolescents with IDDM.

An earlier study by Christiaanse, Lavigne, and Lerner (1989) incorporated patient-related variables into the investigation of factors affecting adherence in child and adolescent asthma patients. The researchers found that the best predictor of adherence in their sample was the interaction of parent-reported child/adolescent behavior
problems in the identified patient and family conflict. More specifically, high levels of family conflict and marked behavior problems were predictive of nonadherence. Christiaanse et al. were careful to point out that children in the sample who exhibited significant behavior problems in the absence of family conflict were at lower risk for adherence difficulties than were those with both behavior problems and conflict issues.

A later study by Kovacs, Goldston, Obrosky, & Iyengar (1992) sought to identify predictors of nonadherence in a sample of IDDM patients. Kovacs and her colleagues followed the cohort of school-aged children for up to nine years to investigate variables related to treatment adherence. This study is unique in the field of pediatric psychology because it assessed deficits in adherence using criteria from the Diagnostic and Statistical Manual of Mental Disorders, Third Edition (DSM-III; American Psychiatric Association, 1980). At the time of participants’ recruitment, the DSM-III defined noncompliance with medical treatment as a pattern of behavior in which the patient demonstrated persistent and serious negligence in following a medical treatment regimen.
Kovacs et al. found that self-esteem, social competence, and family functioning were not predictive of DSM-III-defined nonadherence to the IDDM regimen. The child’s baseline psychological functioning did not predict nonadherence to treatment regimens. Nonadherence was, however, related to patient psychopathology at follow-up. One interpretation of these findings is that child/adolescent psychopathology is not significantly related to adherence when parents are solely responsible for carrying out treatment steps. Psychopathology may be a better predictor of adherence, however, when the patient handles his or her own medical care to a greater degree.

The difference in the relationship between patient psychopathology and adherence based on the patient’s age suggests that age may moderate that relationship between psychopathology and treatment adherence. This difference underscores the fact that researchers studying adherence measure parental adherence when participants are children, and patient adherence when patients are allowed in adolescence to exert greater control over their own regimens.

Kovacs et al. posited that psychiatric disorders may disrupt the individual’s motivation or ability to attend to
his or her health care needs. The authors suggestion that psychopathology is correlated with adherence later in life is consistent with Kinsman, Dirks, and Dahlem’s (1980) work in the adult chronic illness literature citing a similar relationship. It is important to remember that because the Kovacs et al. study (and others like it) is (are) based on correlational data, it is impossible to know the directional influence of these variables. That is, does psychopathology affect adherence, or does sub-optimal adherence breed psychopathology?

The work of Daviss and his colleagues (1995) sought to further examine the role of patient adjustment and psychopathology in adherence. In a sample of adolescent IDDM patients, Daviss et al. measured patient-reported self-esteem, anxiety, and disorder attitudes and parents’ reports of the adolescents’ competence and psychopathology and adherence. Daviss et al. found a positive relationship between adherence and total social competence but did not find adherence to be significantly correlated with psychopathology. The results of the Geiss, Hobbs, Hammersley-Maercklein, Kramer, and Henley (1992) study in a
sample of cystic fibrosis patients bolstered the Daviss et al. notion that adherence is not related to psychopathology.

The inconsistency of the results reported by Geiss et al. (1992), Daviss et al. (1995), Kovacs et al. (1992), and Christiaanse et al. (1989) suggests that the role of psychopathology plays in the adherence process is still unclear. Perhaps there is no relationship between adherence and psychopathology in chronically ill samples of children. It is also possible that no consistent relationship was found between these variables because characteristics of the samples and some methodological features differed among the studies. The Daviss et al. work utilized an adolescent sample with a cross-sectional design. Geiss et al.’s study, though also cross-sectional, used a sample that ranged in age from six months to seventeen years. Christiaanse and her colleagues evaluated the relation between psychopathology and adherence in children ages seven to seventeen years. Kovacs et al. employed a nine-year longitudinal design, whose sample was in middle childhood at the study’s onset and adolescence at the final follow-up.
In summary, researchers studying the associations among child-related variables and adherence suggest that external attributional style is negatively related to adherence (Bennett-Murphy et al., 1997). Christiaanse et al. (1989) found that family conflict and parent-reported child behavior problems interacted to increase the risk of adherence problems. Kovacs et al. (1992) found psychopathology to be related to poor adherence in adolescence. Daviss et al. (1995) and Geiss et al. (1992) found no significant relationship between psychopathology and adherence.

Building An Adherence Model

The previously reviewed literature indicated several variables that are related to treatment regimen adherence. It has been shown that family stress and conflict are negatively related to adherence. Family cohesion, parental involvement, and supportive parenting are positively related to adherence. Approach coping and internal attributional style are also positively correlated with adherence. It is still unclear how patient psychopathology is related to adherence, as this relationship may change across the lifespan.
Ideally, a large-scale research study would incorporate all of these variables and their directional influences into one grand model that would assist researchers and practitioners in understanding and intervening on treatment regimen adherence. It is likely, however, that such a model would be confusing and difficult to interpret simply because of the number of variables and potential interactions included. The model might also be ineffective in predicting adherence across every chronic illness condition. There may also be other variables this model would neglect that would be important in predicting treatment regimen adherence. The remainder of this chapter will briefly review some of the literature regarding one accepted model attempting to explain treatment adherence and propose the model that will be tested in later chapters.

Bond, Aiken, and Somerville (1992) tested the Health Belief Model (HBM) in a sample of adolescents with insulin-dependent diabetes mellitus to assess the effects of patient-related variables on adherence. Most studies test the HBM in adults with chronic illnesses or with negative health habits, such as cigarette smoking. The Bond et al.
study is one of a relative few, to date, that tests this model with chronically ill adolescents.

The HBM (Rosenstock, 1974) was originally developed to account for the enactment of preventive health behaviors. The model posits that health behaviors will be enacted to the extent that: (1) patients are at least minimally knowledgeable and motivated to enact those behaviors; (2) they perceive appreciable susceptibility to the disease or habit in question; (3) they believe the disease or habit is detrimental; (4) they are convinced that adherence is beneficial; and (5) they perceive the barriers (costs) to adherence to be relatively few.

Bond and her colleagues assessed adolescents’ perceptions of the threat posed by IDDM. This construct was defined as a composite of perceived susceptibility and perceived severity. Bond and her colleagues also measured patients’ perceptions of the costs and benefits of adherence; perceived cues indicating the need for medical intervention; and adherence. The researchers found that perceived cues and perceived costs-benefits were significant positive predictors of adherence. The best predictor of adherence, however, was the interaction of perceived costs-benefits and perceived threats. As
predicted by the HBM, Bond and her colleagues found that when the perceived benefit of adherence was high and perceived threat was low, adherence was at its greatest in their sample. When perceived susceptibility and severity (threat) were high, the cost-benefit analysis was unrelated to performance of adherence behaviors. One explanation for this finding offered by Bond and her colleagues is that in cases of chronic illness, threat may relate negatively to adherence because objective threat can not be alleviated. This counters the notion in preventive health regimens that adherence obliterates the objective threat of disease. Thus, the emotional impact of chronic illness is not entirely eliminated by the availability of treatment.

An earlier study by Brownlee-Duffeck et al. (1987) examined the HBM components in a sample of adolescent and adult IDDM patients. Their results showed perceptions of severity and adherence to be negatively related, while perceived susceptibility and adherence showed a positive relationship.

The findings of the Palardy et al. (1998) and Heiby, Gafardi, and McCann (1989) studies are seemingly inconsistent with Bond and her colleagues’ assertion that a negative relationship exists between perceived threat and
adherence. Palardy and her colleagues reported a positive relationship between perceived severity (threat) and adherence. Heiby and her colleagues failed to support the relationship of perceived susceptibility and perceived consequences to adherence. As Palardy, Heiby, and their colleagues did not measure all of the relevant HBM components, it is difficult to speak with certainty about the inconsistency of their results with respect to the Bond et al. and Brownlee-Duffeck et al. studies. This seeming inconsistency, however, does suggest that additional research is needed to clarify the relationship of the HBM components to adherence in IDDM, and in pediatric chronic illness at large.

The Health Belief Model is one of the most comprehensive models predicting treatment adherence from psychosocial variables. This model, however, only takes into account patient-related factors. This is particularly problematic in pediatric populations because, until adolescence, a great deal of a patient’s medical care is provided by the parent. During childhood and adolescence the patient also exists within a family which plays a crucial role in his or her development, a fact that the Health Belief Model seems to completely ignore.
The lack of inclusion of family variables and its seeming applicability to only adolescent and adult populations renders the Health Belief Model ineffective for the purpose of comprehensively accounting for variables that likely predict adherence. Keeping in mind that no model can possibly incorporate every variable that may potentially correlate with adherence, the optimal model would likely include a subset of variables thought to be important in determining how a child or adolescent will adhere to a specific regimen. The optimal model would likely include family stressors, for example, economic changes, divorce, or the addition of new members to the family. It would be important in this model to consider that the relationship between family stress and adherence may be bidirectional because adherence to a treatment regimen, especially with increased complexity, may increase family stress.

This model might also include some aspects of child psychopathology and age, with the understanding that psychopathology’s role in the model may change with age and that different aspects of psychopathology may behave differently in the model. Many studies have documented that treatment regimen adherence tends to worsen from
childhood to adolescence (Anderson et al., 1990; Kovacs et al., 1992; LaGreca et al., 1990). LaGreca and Schuman (1995) suggested, however, that the mechanism by which development affects age is unclear. LaGreca (1990) indicated that the commonly proposed mechanism for this link is that adolescents tend to rebel against their parents and medical authority, leading to poor adherence. This untested mechanism is, at best, speculative (LaGreca & Schuman, 1995).

Another variable that may be important in this model is the individual’s feelings about his or her ability to control the disorder. Bennett-Murphy et al. (1997), Heiby et al. (1989), and Eaton et al. (1992) suggested that, in essence, patients’ feelings about their ability to control a chronic illness were associated with whether they adhered to prescribed regimens. Bond et al. also cited the importance of illness-related attributions in their assessment of the fit of the Health Belief Model in adolescents with insulin-dependent diabetes mellitus.

One factor that has, to date, been largely ignored in the research literature on treatment regimen adherence is secondary gain (or illness behavior encouragement). Matus (1981) defined secondary gain as a condition in which “the
gains derived from being ill outweigh the losses” (p. 332). For example, a child experiencing symptoms of his or her chronic illness may be exempted from doing chores or may receive extra attention from his or her parents. Matus suggested that secondary gain is a factor that may maintain disorders, as effective symptom management and prophylaxis may be impeded when a significant secondary benefit is derived from the illness.

The model comprised of family stress, secondary gain, patient psychopathology, patient attributional style, age, secondary gain, and adherence is shown in Figure 1.1. This model, however, may be too elementary to explain treatment adherence. The Kovacs et al. (1992) study suggested that the relationship between psychopathology and adherence may differ by age, implying that the age likely moderates the relationship between psychopathology and adherence. This would alter the model as shown in Figure 1.2.

It is also reasonable to expect that child psychopathology should be significantly correlated with family stress, as a child’s behavior problems are likely to increase family stress. The resulting model appears in Figure 1.3.
Figure 1.1: Adherence Model: Stage 1
Figure 1.2: Adherence Model: Stage 2
Figure 1.3: Adherence Model: Stage 3

Secondary Gain

Illness Attributions

Age

Child Behavior

Family Stress

Adherence (Refill Rate with Physiological Outcome Covariate)
Just as family stress has been shown to be associated with adherence, Van Sciver and colleagues (1995) suggested that adherence can also increase family stress. Thus the final model might appear as shown in Figure 1.4.

This proposed model will be tested in the pediatric asthma population. The remainder of this chapter will provide background information about asthma and the hypotheses that will be statistically tested in Chapter 3.

**Treatment Adherence in Pediatric Asthma**

Over the past sixty years, a great deal of research has been done to assist scientists and practitioners in understanding asthma. Early research focused on relating the symptoms of asthma to psychological variables. For example, the patient’s wheeze was thought to be an indication of his or her extreme dependence on a maternal figure (Abramson, 1954). More current research on asthma focuses on variables such as family functioning (Cassino et al., 1997), school and work functioning (e. g., Celano & Geller, 1993), and the relation of asthma to psychological disorders, such as panic disorder (e. g., Carr, 1998).

Pharmacotherapy (e. g., theophylline and/or steroid medications) is widely used to treat asthma in children and adults. The medication regimen is a key prophylactic
Figure 1.4: Adherence Model: Stage 4
factor in asthma. Often, however, adult, adolescent, and pediatric patients do not adhere to their medication regimens. Recent studies estimate noncompliance for asthmatics ranging from 30% to 70% (Creer & Bender, 1995). The alarming rate of noncompliance among individuals with asthma necessitates further research into factors that influence nonadherence.

Asthma is a chronic respiratory disease that affects children and adults. Prevalence estimates for pediatric asthma range from 3.9% to 12% in children in the United States (Attaway & Strunk, 1989; Celano & Geller, 1993; Hambley, Brazil, Furrow, & Chua, 1989). Over 3 million children are affected by asthma each year (Lindgren et al., 1992). Young (1994) reported that the age of onset for asthma varies from the first month of life to the adult years. Accounting for more school absenteeism than any other disorder in children under the age of 17, asthma is the most commonly occurring chronic illness in childhood (Ellis, 1988; Gutstadt et al., 1988). It is responsible for 25% of all activity limitations in children (Creer & Bender, 1995) and accounts for more than 10% of all pediatric hospitalizations (Lindgren et al., 1992).
Epidemiological studies have found that the prevalence of asthma in the United States is highest among ethnic minorities, individuals who are poor, and those who live in urban areas (Carter-Pokras & Gergen, 1993; Evans, 1992; Weiss, Gergen, & Cain, 1992). The disorder is believed to affect more boys than girls in childhood and more women than men in adulthood (Ellis, 1988). Morbidity estimates are also higher for children than for adults (Sarafino & Dillon, 1998). Asthma has been described as a “disease of urbanized societies” as its prevalence appears to be highest in the United States, Australia, and Europe (Forero, Bauman, Young, Booth, & Nutbeam, 1996).

An expert panel from the National Institutes of Health has defined asthma in this way:

“Asthma is a chronic inflammatory disorder of the airways in which many cells play a role, including mast cells and eosinophils. In susceptible individuals, this inflammation causes symptoms which are usually associated with widespread but variable airway obstruction that is often reversible, either spontaneously or with treatment, and causes an
associated increase in airway responsiveness to a variety of stimuli” (National Institutes of Health, 1992, p. 1).

This definition underscores three major characteristics of the disease: intermittence, variability, and reversibility. Creer (1983) and Creer and Bender (1995) discussed the fact that the frequency and severity of attacks experienced by an asthmatic may vary within a particular patient and from patient to patient, hence the course of asthma is variable. The reversibility of asthma suggests that airway obstruction remits spontaneously or in response to pharmacotherapy (often a PRN medication such as albuterol). Reversibility, however, is a relative term, as Creer (1983) reported that asthmatics always suffer some level of bronchial obstruction. The intermittence of asthma describes the fact that a patient may experience several attacks in one week or one month and not experience another for several months or years.

**Asthma, Allergic Disorders, and Attention Deficit**

Researchers have reported associations between asthma symptomatology and several psychosocial and psychopathology-related variables. For example, Celano and Geller (1993) suggested that school and work functioning
are compromised when patients experience asthma symptoms. Carr (1998) suggested that asthma and panic disorder symptomatology may be related in that an asthmatic may misinterpret minor symptoms, such as a brief wheeze, as predictive of an impending major asthma attack.

Another area of study that has yielded provocative findings regarding asthma correlates is the line of research examining the associations among asthma, allergic disorders and attentional difficulties. Roth, Beyreiss, Schlenzka, and Beyer (1991) found a statistically significant correlation between allergic skin disorders and attention-deficit/hyperactivity disorder. In their sample, allergy patients were reported to be more frequently inattentive, disruptive, and restless than other non-allergic children. Egger, Carter, Graham, Gumley, and Soothill (1985) and Colquhoun and Bunday (1981), in informal observations of hyperactive children, found allergic disorders and/or asthma to occur in 40% and 80% of their samples respectively. McGee, Stanton, and Sears (1993), however, did not find evidence of such a relationship in a sample of over 700 children and adolescents in New Zealand.
These findings suggest that there could possibly be some “common thread” that ties allergic disorders, including asthma, and attention-related behavior problems. This finding may also be suggestive of a higher incidence of attention-related behavior problems in children and adolescents with asthma and related allergic disorders. Further examination into this area is necessary to clarify the relationship between asthma and attentional difficulties. This line of research might also be extended to include issues of treatment regimen adherence.

**Asthma and Treatment Adherence**

Over the past two decades, researchers have begun to focus on examining adherence to treatment regimens in asthma. Baum and Creer (1986), for example, studied the effects of training and education on adherence. Van Es and her colleagues (1998) conducted focus groups to investigate the relationship between self-management behaviors and adherence. To date, three studies in this area have examined children and adolescents with asthma to probe the relationships among patient- and family-related factors and adherence.

Gavin, Wamboldt, Sorokin, Levy, and Wamboldt (1999) found that the family’s alliance with the child’s physician
was positively related to treatment adherence. The researchers defined treatment alliance as “the ability of an individual and his or her physician to create a positive working relationship” (p. 355). Gavin and her colleagues suggested that the treatment alliance is an important variable to study in individuals with chronic illnesses because ongoing contact with the physician and mutual decision-making are vital. This finding is consistent with the previously cited Voyles and Menendez (1983) assertion that the treatment alliance is a crucial part of the adherence process irrespective of disorder.

One year earlier, Bender, Milgrom, Rand, and Ackerson’s (1998) work indicated that good emotional climate in the family was positively related to treatment adherence in children and adolescents with asthma. Bender et al. also suggested that nonadherence increased linearly with family dysfunction.

The third study suggesting a relationship between psychosocial variables and adherence in individuals with asthma was performed a decade earlier than the work of Gavin et al. (1999) and Bender et al. (1998). As discussed earlier, Christiaanse et al. (1989) reported that family conflict and child behavior problems interacted to
negatively affect treatment adherence. Neither child behavior problems nor family conflict alone, however, was a significant predictor of adherence. Christiaanse and her colleagues suggested that only when levels of family conflict and behavior problems were both high was adherence negatively affected.

In summary, the few existing efforts to uncover psychosocial variables that affect treatment adherence in pediatric asthma patients have revealed that the family’s alliance with the child’s physician and positive emotional climate are positively related to adherence. One study in this area suggested that a child’s behavior problems and the level of conflict in his or her family interacted to affect adherence. Other studies suggested that attention-related behavior problems may be significantly associated with asthma and allergic disorders. Despite these findings, further exploration of the family- and patient-related variables influencing treatment adherence is needed.

To date, none of the adherence literature has examined the influence of family stress on adherence in children and adolescents with asthma. If family conflict, which is seemingly only a subset of family stress, is related to
adherence in children and adolescents, is it not reasonable to hypothesize that family stress itself would be related to adherence?

There has also been no research examining how secondary gain is related to adherence in individuals with asthma. Matus (1981) suggested that adherence is affected by secondary gain in individuals with asthma, yet, again, this proposal has not been researched. Illness-related attributes also have not been evaluated in relation to treatment regimen adherence.

Given the pervasiveness of adherence problems in pediatric asthma, it is important that researchers not only study psychosocial variables but also evaluate them in tandem. The purpose of the current study is to further investigate the direct and interacting effects of psychosocial variables on adherence. The reader may recall that adherence was defined earlier in this chapter as pharmacy refill rate with physiological outcome covaried from it. This study will potentially make a major contribution to the existing literature, as it will provide the basis for a comprehensive model of adherence in pediatric asthma and a novel means of defining and
measuring treatment adherence while also informing treatment efforts across pediatric chronic illness populations.

Hypotheses

(1) It is expected that family stress (impact and frequency) will be negatively related to adherence. This hypothesis is consistent with previous research reviewed earlier in this chapter.

(2) It is also expected that illness-related attitudes or attributions will be significantly related to treatment regimen adherence. That is, individuals with more positive attitudes will be more likely to adhere to treatment regimens.

(3) It is also hypothesized, given previous research, that the relationship between child behavior, specifically attention-related behavior problems, and adherence will be moderated by age. More specifically, adherence and behavior will be unrelated when children are young and negatively related as children advance into adolescence.
(4) It is expected that attention-related behavior problems will be positively related to family stress (impact and severity).

(5) Matus (1981) suggested that secondary gain is related to adherence. It is hypothesized that an inverse relationship exists between adherence and secondary gain. That is, as secondary gain increases, adherence decreases.

(6) It is proposed that secondary gain as reported by the parent will be significantly positively correlated with secondary gain as reported by the child or adolescent.

(7) The interrelationships among adherence, secondary gain, and disease severity have not, as yet, been investigated. A reasonable hypothesis regarding these variables is that severity and secondary gain interact to affect adherence. That is, when secondary gain is high, there will be little to no correlation between severity and adherence. When secondary gain is low,
however, individuals with more severe asthma will tend to be more adherent to treatment regimens.

(8) Another hypothesis related to secondary gain is this one: the relationship between illness-attitudes and adherence should be moderated by secondary gain. More specifically, children with positive attitudes should be more adherent when secondary gain is low. However, when secondary gain is high, adherence should be low regardless of how the child feels about his or her illness.

(9) In accordance with the model proposed earlier in this chapter, it is proposed that the linear combination of family stress, attention-related behavior, secondary gain, illness attitudes, and age will significantly predict adherence.
CHAPTER 2:

METHOD

Participants

Thirty-five children and adolescents (ages eight to seventeen years) treated for asthma were recruited from the pulmonary and allergy clinics at University of Maryland Medical Center (UMMC) in Baltimore, Maryland, from the Medical Center’s Pulmonary and Allergy suburban satellite clinic at Shipley’s Choice in Millersville, Maryland, and from the Medical Center’s suburban satellite clinic in Bel Air, Maryland. The study sample consisted of twenty boys and fifteen girls. Twenty-five of the participant dyads were African-American, nine Caucasian, and one Asian-American.

Approximately 80 patients from the Pulmonary and Allergy Clinic were screened for participation in this study. Forty were enrolled, and 35 completed the entire
study. Only three families refused participation. The Clinic show rate was approximately 60%, with nearly one-half of all patients scheduled meeting age requirements. Of those within the appropriate age group who followed through on their scheduled appointments, 25 to 30% met all study requirements.

**Inclusion Criteria and Related Issues**

In addition to age, the following inclusion criteria were applied to the recruitment of participants: (1) each participant had been diagnosed with asthma; (2) each participant attended the clinic appointment with his or her custodial parent or legal guardian; (3) each participant was to have been prescribed controller medication to treat his or her asthma so that adherence data could be obtained; (4) the child participant was judged by the physician as cognitively advanced enough to accurately complete the requisite questionnaires.

**Materials**

**Illness-Specific Attitudes**

**Child Attitude Toward Illness Scale.** The Child Attitude Toward Illness Scale (CATIS) is a 13-item, Likert-scaled, self-report instrument used to assess how a children evaluate their chronic physical illnesses and
their feelings about their general health (Austin & Huberty, 1993). Response choices for the individual CATIS items range from 1 (very good) to 5 (very bad). In order to obtain a CATIS score, item scores are summed, with items 1, 2, 4, 5, 7, 9, 11, and 13 reversed scored (i.e., 1 = 5, 2 = 4, 3 = 3, 4 = 2, and 5 = 1). This sum is then divided by 13 to yield the CATIS total score. Therefore, total CATIS scores range from 1 to 5. (The CATIS appears in Appendix A.) Greater scores on the CATIS suggest that the child or adolescent participant has negative attitudes about his or her illness and is not hopeful about improving his or her general health.

Internal consistency estimates for the CATIS range from .77 to .82 (Austin & Huberty, 1993; Austin, Huberty, Huster, & Dunn, 1998). Test-retest reliability for the CATIS is .80 over a two-week interval (Austin & Huberty, 1993).

**Secondary Gain**

**Illness Behavior Encouragement Scale.** The Illness Behavior Encouragement Scale (IBES) was developed by Walker and Zeman (1992) to assess perceptions of a parent’s encouragement of a child’s manifestation of chronic illness-specific symptoms, or secondary gain. This Likert-
scaled measure has parallel forms, a child self-report and a parent-report. Response choices for the IBES items on each form ranged from 1 (never) to 5 (always). The IBES total score for each form was calculated by summing the response choices for all 12 items on that form, with items 5 and 6 reversed scored. IBES total score for each form ranged from 12 to 60, with greater scores indicating perceptions of greater illness behavior encouragement. The composite secondary gain score for each dyad was achieved by summing the IBES scores for the parent and child:

Secondary Gain Score = IBES Child + IBES Parent.

The IBES - Child Form appears in Appendix B; the IBES - Parent Form appears in Appendix C.

Internal consistency estimates for the IBES range from .75 to .88. The instrument was normed on a sample of children and their mothers asked to answer the IBES items for cold-related and gastrointestinal symptoms. Parent and child scores were significantly positively correlated, $r = .93$, $p < .01$. Neither the parent- nor the child-reported IBES score was correlated with somatic complaints on the Child Behavior Checklist (CBCL).
Family-Related Factors

Family Inventory of Life Events and Changes. The Family Inventory of Life Events and Changes (FILE) was developed by McCubbin, Patterson, and Wilson (1985) to assess a family’s life stress. The FILE is a 70-item self-report checklist completed by parents. This measure has been used in many studies assessing the influence of family stress on adherence and demonstrates good overall reliability (.72) and test-retest reliability (.72 to .77). The FILE is significantly correlated with several dimensions of the Family Environment Scale (FES): cohesion, independence, organization, and conflict. The FILE appears in Appendix D.

The FILE is comprised of nine subscales: intra-family strains; parenting strains; marital strains; pregnancy/childbearing strains; financial and business strains; work-family transitions strains; illness and family “care” strains; losses; transitions “in and out”; and family legal violations. For each of the 71 FILE items, the respondent indicates whether the event has occurred in his or her family in the past year.

The FILE can be scored in one of two ways. The researcher can assign one point for every item the
respondent endorses. The item scores can be totaled for each subscale and for the instrument as a whole. This yields a frequency score. The second scoring system was developed with the understanding that each life event has a different impact on the family unit; thus, McCubbin and his colleagues assigned scores to each item based on how stressful that event would be for the family. For example, “a parent/spouse died” has a higher stress impact rating than “a member dropped out of school or was suspended.” Summing the impact ratings for endorsed items yields a stress impact score.

Using their normative sample of families with chronically ill children, McCubbin and his colleagues developed comparative normative data over the family cycle. For families of school aged children, the mean stress impact score (using the second scoring system) is 500 with 0 – 265 labeled as “low stress,” 266 – 734 labeled as “moderate stress,” and scores of 735 or greater labeled as “high stress.”

For families of adolescents, the mean impact score in the normative sample was 545, with 0 – 240 indicating “low stress,” 241 – 849 indicating “moderate stress,” and scores over 850 labeled as “high stress.”
The authors suggest that high stress scores indicate an unusually high number of stressors that overburden the family’s psychological and interpersonal resources. Moderate stress scores are “within the normal range of stressors and are typically viewed as non-problematic” (p. 93). Low stress scores suggest that the family is functioning well and may face “an unusually low number of demands” (p. 93).

**Patient Behavior**

**ADHD Rating Scale.** The ADHD Rating was developed by DuPaul (1990) and is a 14-item, Likert-scaled inventory of DSM-defined criteria for diagnosing Attention-Deficit/Hyperactivity Disorder. DuPaul’s measure includes items measuring hyperactivity (items 1, 2, 10, and 14), inattention (items 3, 6, 7, 8, 12, and 13), and impulsivity (items 4, 5, 9, and 11). Response choices for each of the 14 items ranged from 0 (not at all true) to 3 (very much true). The ADHD Rating Scale appears in Appendix E. This measure was selected for this study to obtain a measure of child behavior that was focused on attentional difficulties. Some of the studies cited in Chapter 1 suggested associations among allergic disorders, asthma, and attentional disorders (e.g., Roth et al., 1991, Egger et al., 1985). This writer believes that assessing “pure”
attention-related behaviors will assist in understanding not only how attention-related behaviors work with respect to adherence but also how these behaviors are related to other psychosocial variables already known to be correlates of adherence.

**Demographics**

**Chart Review.** Participants’ medical charts were reviewed to obtain asthma frequency and severity ratings based on National Heart Lung and Blood Institute parameters (NHLBI). The NHLBI classifies asthma based on how often the patient experiences coughing, wheezing and shortness of breath, dividing asthma into two frequency levels: intermittent (symptoms occurring no more that twice weekly) and persistent (symptoms occurring more than twice weekly). The Institute also distinguishes asthma into three severity categories: mild (brief coughing or wheezing episodes that occur less than once daily), moderate (requiring daily medication with nighttime episodes occurring more than once weekly); and severe (continuous symptoms with frequent nighttime symptoms).

Participants’ dates of birth, family history of asthma symptoms, and prescribed medications were also gleaned from the medical chart.
Adherence

Pharmacy Records. As is a common practice at University Hospital, participants’ pharmacy records were reviewed to obtain a measure of medication adherence. Participants’ pharmacy records were obtained and compared against the prescriptions for each prophylactic asthma medication over the six-month period from December 2001 through June 2002. (Prescriptions are routinely photocopied and placed in children’s charts at University of Maryland Medical Center and its satellite clinics.) The participant’s adherence score was computed by taking the ratio of the number of prescriptions filled within thirty days of the last prescription refill date over the total number of refills prescribed over that six-month period.

Peak Flow. A measure of pulmonary functioning was also obtained for each participant. This measure was calculated by dividing the participant’s most recent peak expiratory flow volume by the expected peak expiratory flow, given the patient’s age, height, and weight.

Procedure

A list of eligible asthma patients was obtained weekly from University Hospital Pulmonary and Allergy Clinic staff. On the day of the clinic visit, the pulmonologist or allergist identified children diagnosed with asthma, taking controller medications, and attending the clinic
visit with a custodial parent or legal guardian. Families were then approached in their treatment rooms or in the waiting room by this writer. The child/adolescent participant and the parent/guardian were told about the study and asked if they would be interested in participating. The investigator reviewed the general consent and medical records/pharmacy consent forms, and for those dyads with children ages thirteen and up, the assent form was reviewed and all forms signed. The investigator also obtained information from each family to contact the pharmacy or pharmacies used to fill the index child’s asthma medications. Each family received copies of all of the consent forms once signed. The general consent form, medical/pharmacy record consent, and assent form can be found in Appendices F, G, and H respectively.

After all consent forms were signed, the parent/guardian was given a questionnaire packet containing the IBES-P, FILE, and ADHD Rating Scale. Each child or adolescent was given the IBES-C and CATIS to complete. The investigator notified the family that she would be available to answer any questions that family may have. The questionnaire items were read to three participants who
reported that they were unable to read the items themselves.

Upon completion of the questionnaires, the child was given a $5.00 gift certificate for McDonald’s, and the investigator filled out an entry form to enter the family in a drawing to win either a $50.00 Circuit City or a $50.00 Toys R Us gift certificate.

Participants’ medical charts were reviewed to obtain a rating of the severity and frequency of the child’s asthma, the child’s date of birth, family history of asthma, prescribed asthma medications, and level of current pulmonary functioning.
CHAPTER 3:

RESULTS

Power Analysis

In order to determine the appropriate number of participants needed to test components of the model proposed in Chapter 1, a power analysis was conducted. In the pediatric adherence review by McCants (1999), practical significance estimates (effect sizes) for predicting adherence from a range of psychosocial factors varied from .006 to nearly .40, with the largest effect size estimate being found in a study by Miller Johnson et al. (1994). This study reported a negative relationship between family conflict and adherence to diabetic regimens, with approximately 40% of the variance in adherence explained by family conflict alone.

The present study evaluated the predictive power of five variables (family stress, age, attention-related...
behavior problems, secondary gain, and the child’s attitudes about his or her illness) using adherence with peak flow (physiological outcome) used as covariate as the criterion variable. It is conceivable that the effect size in this study will be at least .40, given the inclusion of stress and the four additional predictors in its regression model. The desired effect size used for the power calculation was .40 ($r = .632$), with desired statistical power set at .80. The alpha-level for this study was set at .05. Using these parameters ($r = .40$, power = .80, and significance level = .05), the suggested sample size is 27 to 28.

**Transformation of the Pharmacy Refill Data**

The pharmacy data collected for each participant were in the form of a ratio:

number of refills purchased/# of refills prescribed.

Because they are proportions, these data are not normally distributed and have nonconstant variance (Cohen and Cohen, 1983). If the underlying sampling distribution for a variable is not normally distributed and the variances are not constant, two of the assumptions of many of the statistical tests that will be employed to analyze these data are violated.
Cohen and Cohen indicated that arc sine transformations help to even out, or “linearize” relationships. The writers suggest that this is the most common of all transformations and is widely used in the behavioral sciences. The arc sine transformation is often used to stabilize the variance of a statistical distribution and to linearize the criterion (dependent) variable, using the following equation:

\[ \text{Transformed } Y = \arcsin \left( \sqrt{Y} \right) \].

In cases in which values of the dependent variable are 1 or 0, it is not possible to compute the transformed Y value as described above; therefore, when pharmacy ratios were equal to 0, the following equation was used in the transformation of Y:

\[ \text{Transformed } Y = \arcsin \left( \frac{1}{4n} \right) \], where n = sample size.

For refill values of Y equal to 1:

\[ \text{Transformed } Y = \arcsin \left( 1 - \frac{1}{4n} \right) \].

The same transformation was performed on the peak flow data which were also defined as proportions (peak expiratory flow volume/expected peak flow).
Summary of Study Variables

A summary of the means and standard deviations for the variables in this study appear in Table 3.1. The average age of the participants was 11 years, 10 months. The normative data from the Family Inventory of Life Events and Changes (FILE) delineated stress categories for families of children and adolescents based on their FILE scores. A summary of these scores can be found in Table 3.2. The majority of the families surveyed in this sample reported stressors whose total impact fell in the moderate range. Only three families in the study had an impact score in the high range. In summary, the majority of the families in the study experienced stressors as would be expected given the age of the index child.

Hypothesis 1

To test the hypothesis that family stress (total number of stressors) is negatively correlated with adherence (pharmacy refills), Pearson product-moment correlation coefficients were calculated and statistically tested. The correlation matrix for the variables in this study appears in Table 3.3.

The correlation of family stress frequency and adherence was calculated using a semi-partial correlation
<table>
<thead>
<tr>
<th>Predictor</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in months)</td>
<td>142.37</td>
<td>34.44</td>
</tr>
<tr>
<td>ADHD Total Score</td>
<td>16.28</td>
<td>11.82</td>
</tr>
<tr>
<td>Family Stress Frequency (Total)</td>
<td>9.38</td>
<td>6.24</td>
</tr>
<tr>
<td>Family Stress Impact (Total)</td>
<td>391.43</td>
<td>270.90</td>
</tr>
<tr>
<td>Illness Attitudes</td>
<td>44.14</td>
<td>5.36</td>
</tr>
<tr>
<td>Child-Reported Secondary Gain</td>
<td>36.69</td>
<td>8.45</td>
</tr>
<tr>
<td>Parent-Reported Secondary Gain</td>
<td>38.28</td>
<td>7.72</td>
</tr>
<tr>
<td>Composite Secondary Gain</td>
<td>74.96</td>
<td>14.70</td>
</tr>
<tr>
<td>Peak Expiratory Flow Volume</td>
<td>.830</td>
<td>.071</td>
</tr>
<tr>
<td>Pharmacy Refill Rate (proportion)</td>
<td>.603</td>
<td>.314</td>
</tr>
</tbody>
</table>

Table 3.1: Summary of Major Variable Means and Standard Deviations
<table>
<thead>
<tr>
<th>Stress Category</th>
<th>Frequency of FILE Impact Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Children</td>
</tr>
<tr>
<td>Low Stress</td>
<td>6</td>
</tr>
<tr>
<td>Moderate Stress</td>
<td>9</td>
</tr>
<tr>
<td>High Stress</td>
<td>3</td>
</tr>
</tbody>
</table>

Table 3.2:
Summary of FILE Scores by Age and Stress Category
<table>
<thead>
<tr>
<th></th>
<th>Stress Impact</th>
<th>Child Sec. Gain</th>
<th>Parent Sec. Gain</th>
<th>Total Sec. Gain</th>
<th>ADHD Total Score</th>
<th>Child Age</th>
<th>Peak Flow</th>
<th>Refill Rate</th>
<th>Illness Atts.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stress Freq.</td>
<td>.990*</td>
<td>.047</td>
<td>-.102</td>
<td>-.027</td>
<td>.313</td>
<td>-.085</td>
<td>-.011</td>
<td>.294</td>
<td>-.025</td>
</tr>
<tr>
<td>Stress Impact</td>
<td>.022</td>
<td>-.115</td>
<td>-.048</td>
<td>.334*</td>
<td>-.091</td>
<td>-.011</td>
<td>.260</td>
<td>-.047</td>
<td></td>
</tr>
<tr>
<td>Child Sec. Gain</td>
<td>.652**</td>
<td>.917**</td>
<td>.372*</td>
<td>-.046</td>
<td>-.415*</td>
<td>.135</td>
<td>-.065</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parent Sec. Gain</td>
<td>.900**</td>
<td>.362*</td>
<td>.081</td>
<td>-.091</td>
<td>-.160</td>
<td>-.094</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Sec. Gain</td>
<td>.404*</td>
<td>.016</td>
<td>-.286</td>
<td>-.006</td>
<td>-.087</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADHD Total Score</td>
<td>-.358*</td>
<td>-.159</td>
<td>-.167</td>
<td>-.046</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child Age</td>
<td>.018</td>
<td>.236</td>
<td></td>
<td>-.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peak Flow</td>
<td>.311</td>
<td>.430</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>-.148</td>
</tr>
</tbody>
</table>

Table 3.3:
Correlation Matrix for Major Study Variables, (n = 35)
coefficient, $sr$, because in Chapter 1 adherence was defined as refill rate with physiological outcome as a covariate. A summary of the semi-partial correlations tested in this study appears in Table 3.4. The correlation between family stress frequency and adherence (refills with outcome removed) was not statistically significant, $sr$ (33) = .29, $p = .085$, $sr^2 = .084$. The squared semi-partial correlation is a measure of practical significance; this one suggests that family stress frequency accounts for 8% of the variance in refill rate after the effect of peak flow is removed. The correlation between family stress impact and pharmacy refills with outcome covaried out is also not statistically significant, $sr$ (33) = .25, $p = .131$, $sr^2 = .065$.

**Hypothesis 2**

To test the second hypothesis that illness-related attitudes or attributions are positively correlated with adherence, a correlation statistic was calculated, $sr$ (33) = .03, $p = .881$, $sr^2 = .001$. This result suggests that illness-related attitudes are unrelated to adherence.

**Hypothesis 3**

The third hypothesis in this study was that the relationship between ADHD-related behavior and adherence
<table>
<thead>
<tr>
<th>Predictor</th>
<th>Correlation (r) with Refill Rate</th>
<th>Semi-partial correlation (sr) with Refill Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Stress Frequency</td>
<td>.29</td>
<td>.29</td>
</tr>
<tr>
<td>Family Stress Impact</td>
<td>.26</td>
<td>.25</td>
</tr>
<tr>
<td>Child Sec. Gain</td>
<td>.14</td>
<td>.00</td>
</tr>
<tr>
<td>Parent Sec. Gain</td>
<td>-.11</td>
<td>.20</td>
</tr>
<tr>
<td>Total Sec. Gain</td>
<td>-.01</td>
<td>.11</td>
</tr>
<tr>
<td>Illness Attitudes</td>
<td>-.11</td>
<td>.03</td>
</tr>
<tr>
<td>Sec. Gain Difference</td>
<td>.35</td>
<td>.26</td>
</tr>
</tbody>
</table>

Table 3.4: Simple and Semi-Partial Correlations for Predictors Related to Refill Rate
would be moderated by age. To test this hypothesis, a hierarchical regression analysis was conducted. This statistical technique was used because, as noted in the Chapter 1, outcome (peak flow) was a variable this writer wished to covary from the criterion measure (refill rate) to obtain a “pure” measure of adherence. By adding the covariate to the model before the other predictors, the variance in the criterion explained by the covariate is removed, and the remaining variance is partialled among the predictors of importance.

In this analysis, first, peak flow (outcome) was entered into the model. Then, ADHD-related behavior was entered into the model to predict pharmacy refills; then age and the total ADHD rating scale score; then age, total ADHD score, and the age x ADHD interaction term. The summary table for this hierarchical analysis is found in Table 3.5.

The effect of peak flow was not statistically significant, \( F(1,33) = 3.549, p = .068, \Delta R^2 = .097 \). When the ADHD rating scale score added, the model remained statistically insignificant, \( F(1,32) = 1.465, p = .235, \Delta R^2 = .040 \). The addition of age to the model also did not yield
### Table 3.5:

Summary of Hierarchical Regression for ADHD-Related Behavior, Age, and Prescription Refill Rate

<table>
<thead>
<tr>
<th>Source</th>
<th>ΔR²</th>
<th>df</th>
<th>F</th>
<th>sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Peak Flow</td>
<td>.097</td>
<td>1,33</td>
<td>3.549</td>
<td>.068</td>
</tr>
<tr>
<td>2. Peak Flow, ADHD Score</td>
<td>.040</td>
<td>1,32</td>
<td>1.465</td>
<td>.235</td>
</tr>
<tr>
<td>3. Peak Flow, ADHD Score, Age</td>
<td>.038</td>
<td>1,31</td>
<td>1.440</td>
<td>.239</td>
</tr>
<tr>
<td>4. Peak Flow, ADHD Score, Age, ADHD x Age</td>
<td>.008</td>
<td>1,30</td>
<td>.292</td>
<td>.593</td>
</tr>
</tbody>
</table>
a statistically significant change in the proportion of remaining refill variance accounted for, $F(1, 31) = 1.440$, $p = .239$, $\Delta R^2 = .038$. Adding the age x ADHD cross-product term to the model already containing the participant’s age and ADHD score, also did not yield a statistically significant change in $R^2$, $F(1, 30) = .292$, $p = .593$, $\Delta R^2 = .008$. These results suggest that the relationship between ADHD-related behavior and adherence is consistent across age.

**Hypothesis 4**

To test the hypothesis that ADHD-related behavior is positively correlated with family stress, both frequency and impact, Pearson product-moment correlation coefficients were calculated. For stress frequency, the correlation coefficient is statistically non-significant: $r(33) = .313$, $p = .067$, $r^2 = .098$. For stress impact, the correlation is only marginally higher but is statistically significant: $r(33) = .334$, $p = .050$, $r^2 = .112$. These results suggest that ADHD-related behavior is not related to the number of family stressors but is predictive of stress when the impact of the stressors is considered.
Hypothesis 5

Matus (1981) suggested that secondary gain is related to adherence. In this study an inverse relationship between these variables was hypothesized. This hypothesis was tested for the child-reported, parent-reported, and composite secondary gain measures separately. The correlation between pharmacy refills with the outcome covariate and child-reported secondary gain was not statistically significant, \( sr(33) = .000, p = .983, r^2 = .000 \). Parent-reported secondary gain also demonstrated a non-significant relationship with adherence, \( sr(33) = .19, p = .262, r^2 = .035 \). The composite secondary gain score (child + parent scores) was also found to be statistically uncorrelated with refill rate with the physiological outcome covariate: \( sr(33) = .10, p = .551, r^2 = .010 \).

Hypothesis 6

It was hypothesized that parent-reported secondary gain would be positively correlated with child-reported secondary gain. This correlation was found to be statistically significant: \( r(33) = .652, p < .001, r^2 = .425 \). Child-reported secondary gain accounts for nearly 43% of the variance in parent-reported secondary gain and appears to increase with parent-reported secondary gain.
It is notable that this correlation is lower than the correlation of .93 cited by Walker & Zeman in the Illness Behavior Encouragement Scale’s normative data.

**Hypothesis 7**

To test the hypothesis that the relationship between severity (as measured by the National Heart Lung and Blood Institute’s scale) and adherence (refill rate) differs based on level of secondary gain (as represented by the secondary gain difference score), a hierarchical regression analysis was conducted. Peak flow was first entered into the model to remove its effect from refill adherence. Then severity was entered into the model; next, the secondary gain composite score; finally, severity, secondary gain, and the severity x secondary gain interaction term. The summary table for this analysis appears in Table 3.6.

Severity was not a significant predictor of refill rate reduced by the peak flow covariate: $F(2,31) = .425, p = .657$. When the secondary gain composite score was added to the model, there no significant increment in proportion of variance explained, $F(1, 30) = .394, p = .535$. The addition of the secondary gain x severity cross-product term to the model accounted for a significant
<table>
<thead>
<tr>
<th>Source</th>
<th>$\Delta R^2$</th>
<th>df</th>
<th>F</th>
<th>sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Peak Flow</td>
<td>.097</td>
<td>1,33</td>
<td>3.549</td>
<td>.068</td>
</tr>
<tr>
<td>2. Peak Flow,</td>
<td>.024</td>
<td>2,31</td>
<td>.425</td>
<td>.657</td>
</tr>
<tr>
<td>Severity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Peak Flow,</td>
<td>.011</td>
<td>1,30</td>
<td>.394</td>
<td>.535</td>
</tr>
<tr>
<td>Sec. Gain,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Sec. Gain,</td>
<td>.172</td>
<td>2,28</td>
<td>3.460*</td>
<td>.045</td>
</tr>
<tr>
<td>Severity,</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sec. Gain x</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* - Test statistic significant at $p < .05$.

Table 3.6:
Summary of Hierarchical Regression Analysis for Secondary Gain Difference, Severity, and Prescription Refill Rate
increment of the remaining refill variance, $F(2, 28) = 3.460, p = .045$. These results suggest that the relationship between severity and refill adherence (with the outcome covariate) is moderated by secondary gain.

**Hypothesis 8**

In order to test the hypothesis that illness-related attitudes moderate the relationship between pharmacy refill rate and secondary gain, a hierarchical regression was conducted, with peak flow entered first; followed by illness attitudes; illness attitudes and secondary gain; and finally illness attitudes, composite secondary gain, and the illness attitudes x secondary gain interaction term. The summary of this analysis appears in Table 3.7.

Illness attitudes was not a significant predictor of adherence: $F(1, 32) = .024, p = .877, \Delta R^2 = .001$. The secondary gain score, when added to the model, did not significantly add to the prediction of adherence rate: $F(1, 31) = .361, p = .552, \Delta R^2 = .010$. The interaction between illness attitudes and secondary gain score, when added, did not facilitate a significant increment in refill rate explained: $F(1, 30) = 2.993, p = .094, \Delta R^2 = .081$. 

82
<table>
<thead>
<tr>
<th>Source</th>
<th>ΔR²</th>
<th>df</th>
<th>F</th>
<th>sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Peak Flow</td>
<td>.097</td>
<td>1,33</td>
<td>3.549</td>
<td>.068</td>
</tr>
<tr>
<td>2. Peak Flow, Attitudes</td>
<td>.001</td>
<td>1,32</td>
<td>.024</td>
<td>.877</td>
</tr>
<tr>
<td>3. Peak Flow, Attitudes, Sec. Gain</td>
<td>.010</td>
<td>1,31</td>
<td>.361</td>
<td>.552</td>
</tr>
<tr>
<td>4. Peak Flow, Attitudes, Sec. Gain, Attitudes x Sec. Gain</td>
<td>.081</td>
<td>1,30</td>
<td>2.993</td>
<td>.094</td>
</tr>
</tbody>
</table>

Table 3.7:

Summary of Hierarchical Regression for Illness-Related Attitudes, Secondary Gain, and Refill Adherence
This result suggests that secondary gain does not moderate the relationship between illness-related attitudes and refill rate.

Hypothesis 9

In order to test the model proposed in Chapter 1, a multiple linear regression analysis was conducted. In the original model, it was proposed that the relationship between ADHD-related behavior and refill rate was moderated by age. Earlier in this chapter, this moderating relationship was found to be statistically insignificant; therefore, it will be left out of the model tested in this section. Peak flow was once again added first to the model as a covariate.

The results of this multiple linear regression suggest that the optimal linear combination of family stress (impact), ADHD-related behavior, secondary gain score, illness attitudes, and participant’s age is a not significant predictor of pharmacy refill rate when outcome (peak flow) is used as a covariate: $F (5, 28) = 1.515, p = .217, \Delta R^2 = .289$. The summary of this analysis appears in Table 3.8.
<table>
<thead>
<tr>
<th>Source</th>
<th>$\Delta R^2$</th>
<th>df</th>
<th>F</th>
<th>sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Peak Flow</td>
<td>.097</td>
<td>1,33</td>
<td>3.549</td>
<td>.068</td>
</tr>
<tr>
<td>2. Peak Flow, Age, ADHD Total, Stress Impact, Attitudes, Sec. Gain</td>
<td>.289</td>
<td>5,28</td>
<td>1.515</td>
<td>.217</td>
</tr>
</tbody>
</table>

Table 3.8: Summary of Hierarchical Regression Analysis for the Full Adherence Model Summary
Supplemental Analyses

In order to further probe the relationships hypothesized in Chapter 1, all of the statistical analyses completed using peak flow as a covariate were repeated using peak flow as the sole criterion variable. None of these analyses reached statistical significance ($p < .05$). It can, therefore, be concluded that few of the psychosocial variables and their proposed inter-relationships predict the defined adherence measure (refill rate with the outcome covariate) or peak flow (physiological outcome).

Summary

The results of the analyses in this chapter suggest that neither family stress (impact or frequency), illness-related attributions, nor secondary gain (child- or parent-reported, composite or difference) is significantly correlated with adherence, which was defined in Chapter 1 as the variation in refill rate that remains after partialling out physiological outcome (peak flow).

Family stress frequency is also not significantly correlated with ADHD-related behavior problems; stress impact, however, is significantly correlated with adherence as defined in Chapter 1.
The results of the current analyses also suggest that the age of the child does not moderate the relationship between ADHD-related behavior and adherence. The analyses do suggest, however, that the secondary gain composite score is a significant moderator of the relationship between severity and adherence, as proposed in Chapter 1.

The analyses discussed in this chapter do, however, suggest that secondary gain moderates the relationship between adherence and severity. Specifically, when secondary gain is high, severity and adherence are uncorrelated. When secondary gain is low, severity is positively related to adherence.

The final analysis in this chapter tested the larger model proposed in Chapter 1. The results of the analysis suggest that the model containing age, stress impact, attitudes about illness, ADHD-related behavior, and secondary gain composite do not effectively predict adherence as defined as refill rate with peak flow used as a covariate.
CHAPTER 4:

DISCUSSION

The goal of the present study was to develop a model for studying treatment adherence in pediatric chronic illness and to test that model in a sample of children and adolescents with asthma. Analyses performed on the present data yielded very mixed results with respect to the experimental hypotheses.

Family-Related Variables

In this sample of asthmatic children and adolescents family stress was not correlated with adherence as defined by refill rate less the physiological outcome covariate. This finding is inconsistent with the Van Sciver, D’Angelo, Rappaport, & Woolf (1995) assertion that family stress is not only related to adherence, but that adherence may exacerbate family stress. This discrepancy may be related to differences in the demographic characteristics of the
samples in question. For example, the majority of the current sample had mild or moderate asthma; the number of severe asthma cases was limited. In the Van Sciver et al. sample severity was more evenly distributed, thus, likely more representative of the true state of the population of individuals with asthma. It is possible that the restricted range of stress ratings (as only three families demonstrated stress impact scores in the “high” range), taken with the restricted range of severity ratings in this sample attenuated the correlation between adherence and family stress.

**Patient-Reported Illness Attitudes**

The results of the current study suggest that participants’ illness-related attitudes were also not significantly correlated with adherence. This result is inconsistent with the results from Heiby, Gafardi, and McCann (1989) and Bennett-Murphy et al. (1997), suggesting that adolescents with negative attributions about their disorders would be less adherent to their treatment regimens. This result was also inconsistent with Bond et al. (1992) finding in a test of the Health Belief Model that the patient’s perceptions of a chronic illness were related to adherence. The inconsistency in this study is
likely attributable to several major issues. The first is that previous studies examined child-related attitudes in association with child-related adherence behavior. The current study examined child-related attitudes with respect to parent-related behaviors. This fact alone would account for the discrepancy between the findings of previous studies and this one. Perhaps if child-facilitated adherence had been assessed in the current study, a significant correlation with child-reported illness-related attitudes may have been found.

A second issue that might explain the inconsistency between the results of this and previous studies is that illness-related attributions in the current study were measured using a short questionnaire that assessed not only attributions, for example, “How often do you feel you will always be sick,” but also the child’s general feelings about the disorder, for example, “How good or bad do you feel it is to have asthma?” This difference suggests that perhaps other studies were measuring “pure” attributions, while this one measured how the child feels about asthma in general and about his or her own experience with asthma.

A third consideration is that in the Bennett-Murphy et al. and Bond et al. samples, as well as others, the
researchers measured adolescents’ adherence using a physiological outcome, glycosylated hemoglobin. In Chapter 1 of this work, the issue of how to measure adherence was discussed. Hentinen and Kyngas (1996) criticized the use of direct assays, such as glycosylated hemoglobin, to measure adherence, suggesting that they do not assist psychologists in understanding where they can intervene to assist patients in improving their adherence. That is, the psychologist is unable to directly manipulate a patient’s blood glucose levels but can assist the patient in making lifestyle changes that may affect the patient’s ultimate physiological outcome.

Child Behavior, ADHD, and Allergic Disorders

In a longitudinal study investigating the relationship between child psychopathology and treatment adherence, Kovacs, Goldston, Obrosky, & Iyengar (1992) found that child psychopathology was only related to adherence when participants were adolescents. This suggests that age may moderate the relationship between adherence and child psychopathology. The results of the current study did not support the Kovacs et al. findings. Child behavior, as measured by the ADHD Rating Scale, and refill rate with the physiological outcome covariate were statistically
unrelated regardless of the child’s age in the current sample. As the range of child behavior/psychopathology was restricted to only ADHD-related behavior in a non-clinical sample, it is likely that any correlation between psychopathology and adherence in this study is attenuated due to these restrictions. It is a statistical fact that correlations are often attenuated when the range of either of the variables involved is restricted (Cohen & Cohen, 1983).

It was also hypothesized in Chapter 1 that not only would child behavior demonstrate a moderated relationship to adherence but also that child behavior would be positively related to family stress. The results of the analyses in Chapter 3 suggest that in the current non-clinical sample of children and adolescents with asthma, attention-related behavior problems was a significant predictor of family stress only when the impact component of stress was considered. It is unclear, however, whether these behavior problems create family stress or if the child’s asthma and attention-related behavioral issues work in tandem to increase stress. If asthma and attention-related behavior problems are significantly correlated, as suggested by Roth et al. (1991), Egger et al. (1985), and
Colquhoun and Bunday (1981), it would make conceptual sense that the two variables may work in tandem to increase stress. That is, having a child with attention-related difficulties and asthma likely increases perceived parental stress.

Secondary Gain

Matus (1981) suggested that secondary gain is related to treatment adherence in asthmatics. That is, individuals who accrue some secondary benefit (e.g., special treatment from a parent) as a result of experiencing asthma symptoms are likely to be less adherent than individuals who do not accrue such benefits. The results of this study do not support that hypothesis. As suggested previously, this result may be attributable to the fact that secondary gain accrued by the child is being correlated with a criterion variable (the parent’s frequency of refilling the child’s prescriptions) that may have little to do with the child’s motivation to take his or her medication.

Child-reported secondary gain was found to be significantly correlated with parent-reported secondary. That is, children who acknowledged the secondary benefits of having asthma had parents who acknowledged providing such benefits. This result may challenge the notion that
self-report data are notoriously susceptible to socially desirable responding. If this result were consistent with the notion of social desirability, parents would have denied providing secondary gain despite the fact that their children acknowledged receiving some secondary benefits. The significant correlation between parent- and child-reported secondary gain may also indicate that parents do not realize the secondary benefits they provide to their sick children.

Composite secondary gain (child-reported + parent-reported) was also found to moderate the relationship between asthma severity and adherence, such that when perceptions of secondary gain are high, there is no significant relationship between severity and adherence. More specifically, when there is a secondary benefit to being sick (e.g., having asthma attacks), there is no reliable pattern of medication refill rate. Perhaps this suggests that parents are likely to dismiss the child’s symptoms and the importance of the medication when they believe their children are “faking sick” or “just doing it to get attention.” This finding, although quite disturbing, suggests that the health care system needs to educate families about the secondary benefits of chronic
illnesses, discerning the difference between real and feigned symptoms, and the importance of providing medication whenever the child is in need.

The second component of this important moderated relationship is somewhat more promising, suggesting that when secondary gain is low, individuals with more severe asthma are more apt to adhere to their medication regimens. This writer believes that medical professionals would be pleased if all of their patients were perfectly adherent to their medication regimens. If, however, there is to be a discrepancy in adherence based on level of severity, a positive correlation between severity and adherence (i.e., greater adherence correlated with more severe asthma) is likely a desirable result.

Adherence Model

The overarching goal of this project was to propose and test a model predicting adherence (refill rate with the outcome covariate) from several family- and child-related psychosocial variables. The proposed model appears in Figure 1.4 in Chapter 1. The linear regression analysis testing that model yielded mixed results. When peak flow was partialled out of refill rate, the child’s age, family stress (impact), illness attitudes, and the secondary gain
difference did not significantly increment the proportion of remaining refill rate explained.

This result challenges the notion that physiological outcome should be considered a nuisance, or control, variable in the measurement of adherence. The result also leads this writer to consider whether refill rate without physiological outcome is a construct of importance in the treatment of individuals with adherence difficulties. In diabetic populations a physiological outcome measure (glycosylated hemoglobin) is one of the best means of assessing adherence. Because of the variability, intermittence, and reversibility of asthma and the multifaceted nature of its treatment, physiological outcome may not be the best means of understanding the process of adherence. If a researcher completely ignores physiological outcome when studying adherence, however, is he or she potentially missing a large component of the phenomenon of adherence. This begs the question, will the patient adhere to a treatment regimen if not motivated by the possibility of improving or maintaining his or her physiological functioning? The fact that the regression model containing peak flow as a predictor accounts for more variance in refill rate than does the model with peak flow
as a covariate lends further support to the notion that physiological outcome is an important part of the phenomenon of adherence that should not be ignored in future studies.

Limitations

First, it must be said that some of the questionnaire measures used in this study were different from those employed in other studies. Some of the measures used in this study were selected because they were relatively brief and self-explanatory, thereby, improving the likelihood that the dyads participating would complete them accurately. Others, such as the Illness Behavior Encouragement Scale, were used because there were no other instruments like them in existence in the field. Some of the other studies reviewed to assist in building the adherence model used more extensive measures or repeated administrations of measures to collect their data, however, the Child Attitude Toward Illness Scale and Family Inventory of Life Events and Changes were used in a subset of the studies reviewed in Chapter 1.

Another important consideration of the current study related to its instrumentation was the use of a parent-related variable (refill rate) as the major criterion
variable. In Chapter 1 many of the study hypotheses were stated assuming that both the predictor and criterion were child-related variable. For example, it was proposed that participants accruing secondary gain should be less likely to adhere to their medication regimens because symptom reduction would decrease their secondary benefits. In adult populations, such a relationship would be easy to study as the individual who directly benefits from the secondary gain is the one who is responsible for refilling his or her own prescriptions. In pediatric populations, however, a child or adolescent (the beneficiary of secondary gain) is unlikely to be held responsible for filling his or her own prescriptions. Thus, the correlation between any child-reported variable, such as secondary gain and adherence, which in this study is more of a parent-related behavior, may not be as strong expected. Correlating these two types of variables may also lead to difficulties with interpretation of any statistical results. Future studies should attempt to measure the child’s adherence directly rather than the parent’s motivation to pick up the child’s medication or supplies.
A frequently cited limitation that is common to this study is the use of a cross-sectional design. This research design restricted the researcher to gaining only a “snapshot” of many of the phenomena of interest. The majority of the studies reviewed in Chapter 1, however, used a similar design. Future research efforts would be most useful in assisting the medical profession in understanding adherence by studying the process and its correlates over a longer period of time, for example, over a decade following the individual’s diagnosis with a chronic illness. This may also assist researchers in understanding how the parent’s role in the adherence process and the relationships among other psychosocial variables (for example, children’s illness-related attitudes, secondary gain, and behavior problems) changes over the lifespan.

Another limitation of this study is exclusion of other chronic illness groups in the study. The results of this study are safely generalizable only to pediatric asthma populations because it is not clear whether any of the relationships found here are applicable to diabetics, cancer patients, or other groups, for example, because these groups were not considered in this study. Future
research efforts should examine the physiological and psychosocial variables from this study as they relate in other disease populations.

A final note on adherence is this: despite the careful selection of pharmacy refill rate with the physiological outcome (peak flow) covariate as a proxy for treatment regimen adherence, this effort may be no closer to learning the truth about adherence than were previous studies. In the literature review in Chapter 1, it was suggested that adherence and compliance were two different constructs, as adherence was suggested by Voyles and Menendez (1983) and Jay (1997) to be more representative of the doctor-patient partnership that works to improve therapeutic success. In this study, adherence was measured using only information about medication refills and physiological outcome. The doctor-patient partnership was never assessed. Future research studies in this area would contribute greatly to the field of pediatric psychology by assessing medication refill rate, outcome, and the doctor-patient partnership and finding an optimal way to combine these data to assist healthcare workers and patients in improving their adherence and long-term health outcomes.
REFERENCES


control of adolescents and adults with diabetes mellitus. Journal of Consulting and Clinical Psychology, 55, 139 – 144.


APPENDIX A:

CHILDREN’S ATTITUDE TOWARD ILLNESS SCALE
The next 13 questions will help us to understand how you feel about having asthma.

Please answer all of the questions as best you can.

1. How good or bad do you feel it is that you have asthma?
   
   1     2       3      4     5
   Very         Very
   Good  Good    Fair    Bad  Bad

2. How fair is it that you have asthma?
   
   1     2       3      4     5
   Very   Pretty  Somewhat   Not   Very
   Fair  Fair    Fair      Fair  Unfair

3. How happy or sad is it for you to have asthma?
   
   1     2       3      4     5
   Very         Very
   Happy  Happy    Fair    Sad  Sad

4. How bad or good do you feel it is to have asthma?
   
   1     2       3      4     5
   Very          Very
   Good  Good    Fair    Bad  Bad

5. How often do you feel that your asthma is your fault?
   
   1     2       3      4     5
   Always     Very Often  Sometimes  Rarely  Never
6. How often do you feel that your asthma keeps you from doing the things you like to do?

1 2 3 4 5
Always Very Often Sometimes Rarely Never

6. How often do you feel that you will always be sick?

1 2 3 4 5
Always Very Often Sometimes Rarely Never

7. How often do you feel that your asthma keeps you from starting new things?

1 2 3 4 5
Always Very Often Sometimes Rarely Never

8. How often do you feel different from others because of your asthma?

1 2 3 4 5
Always Very Often Sometimes Rarely Never

9. How often do you feel bad because you have asthma?

1 2 3 4 5
Always Very Often Sometimes Rarely Never

10. How often do you feel sad about being sick?

1 2 3 4 5
Always Very Often Sometimes Rarely Never

11. How often do you feel happy even though you have asthma?

1 2 3 4 5
Always Very Often Sometimes Rarely Never
12. How often do you feel just as good as other kids your age even though you have asthma?

1 Always  2 Very Often  3 Sometimes  4 Rarely  5 Never
APPENDIX B:

ILLNESS BEHAVIOR ENCOURAGEMENT SCALE, CHILD VERSION
What happens when you are sick?

The next questions are about what your parents do when you have an asthma attack. For each question, choose one of these answers.

- **Never** means that your parents never do this.
- **Seldom** means that your parents only do this once in a while.
- **Sometimes** means that your parents do this some of the time.
- **Often** means that your parents usually do this.
- **Always** means that your parents always do this.

1. How often do your parents let you stay home from school when you have an asthma attack?

   - 1 Never
   - 2 Seldom
   - 3 Sometimes
   - 4 Often
   - 5 Always

2. How often do your parents say you do not have to do regular chores such as taking out trash or cleaning up when you have an asthma attack?

   - 1 Never
   - 2 Seldom
   - 3 Sometimes
   - 4 Often
   - 5 Always

3. How often do your parents say you don’t have to finish all of your homework when you have an asthma attack?

   - 1 Never
   - 2 Seldom
   - 3 Sometimes
   - 4 Often
   - 5 Always

4. How often do your parents bring you special treats, or little gifts when you have an asthma attack?

   - 1 Never
   - 2 Seldom
   - 3 Sometimes
   - 4 Often
   - 5 Always

5. How often do your parents insist that you go to school when you have an asthma attack?

   - 1 Never
   - 2 Seldom
   - 3 Sometimes
   - 4 Often
   - 5 Always
6. How often do your parents still expect you to do chores and homework when you have an asthma attack?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>Seldom</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
</tbody>
</table>

7. How often do your parents take you to the doctor when you have an asthma attack?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>Seldom</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
</tbody>
</table>

8. How often do your parents spend more time than usual with you when you have an asthma attack?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>Seldom</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
</tbody>
</table>

9. How often do your parents give you special privileges or let you do things you aren’t usually allowed to do when you have an asthma attack?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>Seldom</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
</tbody>
</table>

10. How often do your parents stay home from work or come home early (if they don’t work, how often do they stay home instead of going shopping or running errands) when you have an asthma attack?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>Seldom</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
</tbody>
</table>

11. How often do your parents pamper or spoil you when you have an asthma attack?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>Seldom</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
</tbody>
</table>

12. How often do your parents tell other people in the family not to bother you or to be especially nice to you when you have an asthma attack?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>Seldom</td>
<td>Sometimes</td>
<td>Often</td>
<td>Always</td>
</tr>
</tbody>
</table>
APPENDIX C:

ILLNESS BEHAVIOR ENCOURAGEMENT SCALE, PARENT VERSION
What happens when your child is sick?

The next questions are about what you do when your child has asthma attacks. For each question, choose one of the answers.

Never means that you never do this.
Seldom means that you only do this once in a while.
Sometimes means that you do this some of the time.
Often means that you usually do this.
Always means that you always do this.

1. How often do you let your child stay home from school when he or she has an asthma attack?

1       2       3        4        5
Never    Seldom    Sometimes  Often    Always

2. How often do you say your child does not have to do regular chores such as taking out the trash or cleaning up when he or she has an asthma attack?

1       2       3        4        5
Never    Seldom    Sometimes  Often    Always

3. How often do you say your child does not have to finish all of his or her homework when he or she has an asthma attack?

1       2       3        4        5
Never    Seldom    Sometimes  Often    Always

4. How often do you bring your child special treats, or little gifts when he or she has an asthma attack?

1       2       3        4        5
Never    Seldom    Sometimes  Often    Always

5. How often do you insist that your child go to school when he or she has an asthma attack?

1       2       3        4        5
Never    Seldom    Sometimes  Often    Always
6. How often do you still expect your child to do chores and homework when he or she has an asthma attack?
   1 2 3 4 5
   Never Seldom Sometimes Often Always

7. How often do you take your child to the doctor when he or she has an asthma attack?
   1 2 3 4 5
   Never Seldom Sometimes Often Always

8. How often do you spend more time than usual with your child when he or she has an asthma attack?
   1 2 3 4 5
   Never Seldom Sometimes Often Always

9. How often do you give your child special privileges or let him or her do things he or she is not usually allowed to do when he or she has an asthma attack?
   1 2 3 4 5
   Never Seldom Sometimes Often Always

10. How often do you stay home from work or come home from work early (if you don’t work outside the home, how often do you stay home instead of going out or running errands, etc.) when he or she has an asthma attack?
    1 2 3 4 5
    Never Seldom Sometimes Often Always

11. How often do you pamper or spoil your child when he or she has an asthma attack?
    1 2 3 4 5
    Never Seldom Sometimes Often Always

12. How often do you tell other people in the family not to bother your child or to be especially nice to your child when he or she has an asthma attack?
    1 2 3 4 5
    Never Seldom Sometimes Often Always
APPENDIX D:

FAMILY INVENTORY OF LIFE EVENTS AND CHANGES


**FILE**

Family Inventory of Life Events and Changes

Hamilton L. McCubbin  
Joan M. Patterson  
Lance R. Wilson

**APOSE**

Over their life cycle, all families experience many changes as a result of normal growth and development of members and due to external circumstances. The following list of family life changes can happen in a family at any time. Because family members are connected to each other in some way, a life change for any one member affects all the other persons in the family to some degree.

"FAMILY" means a group of two or more persons living together who are related by blood, marriage or adoption. This includes persons who live with you and to whom you have a long term commitment.

**INSTRUCTIONS**

**DO THE CHANGE HAPPEN IN YOUR FAMILY?**

Please read each family life change and decide whether it happened to any member of your family—including you. During the last year, first, decide if it happened any time during the last 12 months and then check YES or NO.

<table>
<thead>
<tr>
<th>FAMILY LIFE CHANGES</th>
<th>DID THE CHANGE HAPPEN IN YOUR FAMILY?</th>
<th>DURING LAST 12 MONTHS</th>
<th>YES</th>
<th>NO</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Increase in the amount of &quot;nursing activities&quot; which the family was involved in</td>
<td>35</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Increase in the number of problems or issues which don't get resolved</td>
<td>35</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Increase in the number of tasks or chores which don't get done</td>
<td>35</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Increased difficulty managing children (2-6 yrs)</td>
<td>35</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Increased difficulty managing sibling children (6-12 yrs)</td>
<td>35</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Increased difficulty managing adolescent (12-17 yrs)</td>
<td>35</td>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TOTAL:** 180

Please turn over and complete #2
<table>
<thead>
<tr>
<th>FAMILY LIFE CHANGES</th>
<th>DID THE CHANGE HAPPEN IN YOUR FAMILY?</th>
<th>FAMILY LIFE CHANGES</th>
<th>DID THE CHANGE HAPPEN IN YOUR FAMILY?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BEFORE</td>
<td>12 MONTH</td>
<td>YES/NO</td>
</tr>
<tr>
<td>41. PREGNANCY AND CHILDREN CARE STRAINS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>42. Someone had a new or difficult pregnancy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>45. An unmarried member became pregnant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>48. A member gave birth to or adopted a child</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50. A member gave birth to or adopted a child</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>52. Family income or wealth increased or decreased</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>54. Change in employment status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>56. A member started a new business</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>58. A member started a new business</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>60. Purchased a new car or major home improvement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>62. A member purchased a car or major home improvement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>64. Increased stress on family income or economic status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66. Increased stress on family income or economic status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>68. Increased stress on family income or economic status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>70. Increased stress on family income or economic status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>72. A member lost or quit a job</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>74. A member retired from work</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>76. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>78. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>80. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>82. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>84. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>86. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>88. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>90. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>92. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>94. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>96. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>98. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>102. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>104. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>106. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>108. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>110. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>112. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>114. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>116. A member was hospitalized</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX E:

ADHD RATING SCALE
# ADHD Rating Scale

Child's Name ____________________________  Age ______  Grade ______
Completed by ____________________________

Circle the number in the one column which best describes the child.

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Just a little</th>
<th>Pretty much</th>
<th>Very much</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Often fidgets or squirms in seat.</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Has difficulty remaining seated</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Is easily distracted</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Has difficulty awaiting turn in groups</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Often blurts out answers to questions</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Has difficulty following instructions</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Has difficulty sustaining attention to tasks</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Often shifts from one uncompleted activity to another</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Has difficulty playing quietly</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10. Often talks excessively</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11. Often interrupts or intrudes on others</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12. Often does not seem to listen</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13. Often loses things necessary for tasks</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14. Often engages in physically dangerous activities without considering consequences</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Note. From The ADHD Rating Scale: Normative Data, Reliability, and Validity by G. J. DuPaul, 1990, unpublished manuscript, University of Massachusetts Medical Center, Worcester. Reprinted by permission of the author. This form may be reproduced for personal use.
APPENDIX F:

RESEARCH CONSENT FORM
RESEARCH CONSENT FORM

Project Title: An Investigation of Variables Related to Treatment in Pediatric Asthma

Principal Investigators: Vicki J. Tepper, Ph.D. (410) 706-6538
Co-Investigators: Kellie McCants, M.A., (410) 578-2619
Mary Beth Bollinger, D.O., (410) 706-2443
Thomas Linscheid, Ph.D. (614) 722-4700

PURPOSE OF THE STUDY
The purpose of this study is to examine how family- and child-related behaviors are related to the treatment of asthma in children and adolescents. This study is a joint project involving the Department of Pediatrics at the University of Maryland School of Medicine and the Department of Psychology at The Ohio State University. You and your child are being asked to participate in this study because:

1. your child has been diagnosed with asthma;
2. your child is between the ages of 8 and 17 years of age;
3. your child receives medical services in this clinic to care for his or her asthma.

BENEFITS/RISKS
Your participation in this study may not directly benefit you or your child, but will help the researchers to determine ways in which the medical community can improve their strategies for caring for children and adolescents with asthma. You may also help us to identify sources of stress that are common to families of children with asthma and those that are common to families of children with chronic illness in general.

The risks related to this study are very few. However, while filling out some of the questionnaires, you may experience negative feelings while thinking of difficult events in your life. If you become very distressed by this, a list of mental health counselors can be provided to help you to deal with your discomfort.

PROCEDURES
If you choose to participate in the study, you and your child will be asked to complete a short packet of questionnaires asking about your family, your child’s feelings about having asthma, and your response, as well as your child’s, to the child’s asthma attacks. You will also be asked to provide the research team permission to access your child’s medical and pharmacy records. Information obtained from your child’s medical record will include a physician’s rating of the severity of your child’s asthma. The information provided by the pharmacy will be an account of the refill history for your child’s asthma medication. This study will require only about 35 minutes of your time during this clinic visit, and the questionnaires can be completed during your “down time.”
CONFIDENTIALITY
The information we collect on the questionnaires during this visit will be used only for research purposes and will not be shared with your healthcare provider. This information will be kept strictly confidential and will not affect the medical care your child receives now or at any time in the future. Only Dr. Tepper (the principal investigator in the study) and Ms. McCants will have access to the information you and your child provide during the study. With the exception of the consent forms, all study-related paperwork will be identified by participant number. After the pharmacy records have been reviewed, the consent forms will be separated from your completed questionnaires. All research-related information will be coded and entered into a computer program, stored apart from your child’s medical records; the questionnaire measures will be retained in a locked file cabinet in Ms. McCants’ office for 1 year then shredded and disposed of. Neither your name nor your child’s will be stored with the data (after the pharmacy records are obtained). Identifying information, such as names and birthdates, will not be used in any reports or publications related to the research data.

RIGHT TO WITHDRAW
Your participation in this study is voluntary. You are not obligated to participate in this research. You are free to withdraw your consent at any time. Refusal to participate will not affect your current or future medical care in any way at the University of Maryland Medical System (or any of its subsidiaries).

COSTS/COMPENSATION
Upon completion of this study, your family will receive $5 worth of McDonald’s or Wendy’s gift certificates. Your family will also be entered in a drawing for a chance to win one of 2 $50 gift certificates from Circuit City or Toys R Us. If your family is one of the two selected to win one of the $50 gift certificates, you will be contacted by phone by a member of the research team upon completion of the study data collection.

OR

The Office of Research Risk Protection
The Ohio State University
Third Floor, Research Foundation Building
1965 Keesey Road
Columbus, Ohio 43210-1063
(614) 688-4792

UNIVERSITY STATEMENT (Minimal Risk Studies)
The University is committed to providing subjects of its research all rights due them under State and federal law. You give up none of your legal rights by signing this
consent form or by participating in the research project. Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

The research described in this consent form has been classified as minimal risk by the University of Maryland Institutional Review Board (IRB), a group of scientists, physicians, and other experts. The Board's membership includes persons who are not affiliated with the University and persons who do not conduct research projects. The Board's decision that the research is minimal risk does not mean that the research is risk-free, however. Generally speaking, you are assuming the risks of research participation, as discussed in the consent form. But, if you are harmed as a result of the negligence of a research, you can make a claim for compensation. If you believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact the IRB for more information about claims procedures.

Institutional Review Board
University of Maryland at Baltimore
685 West Baltimore Street
Baltimore, Maryland 21201
(410) 706-5037
If you agree to join this study, please sign your name below.

NOT VALID WITHOUT THE
IRB STAMP OF CERTIFICATION

Subject's signature

Date:

Date:

Date:

Date:

Date:

Date:

Signature of Parent/Legally Appointed Guardian
(When Applicable)

Signature of Investigator or Authorized
Representative obtaining informed consent

Witness to Consent procedures
(Optional unless subject is illiterate, or unable to sign)

Investigator reviewed consent form and is aware of Subject
enrollment.

*Optional unless subject is illiterate, or unable to sign.

NOTE: Copies of this Consent Form with original signatures must be a) retained on file
by the Principal Investigator; and b) given to the subject. A copy must also be deposited
in the patient's medical record (if any).
APPENDIX G:

MEDICAL/PHARMACY RECORD RESEARCH CONSENT FORM
MEDICAL/PHARMACY RECORD RESEARCH CONSENT FORM

Project Title: An Investigation of Variables Related to Treatment in Pediatric Asthma
Principal Investigator: Vicki J. Tepper, Ph.D. (410) 786-6538
Co-Investigators: Kellie McCaslin, M.A. (410) 578-2619
Mary Beth Bollinger, D.O. (410) 786-2443
Thomas Linscheid, Ph.D. (614) 722-4700

The purpose of this study is to examine how family and child-related behaviors are related to the treatment of asthma in children and adolescents. This study is a joint project involving the Department of Pediatrics at the University of Maryland School of Medicine and the Psychology Department at The Ohio State University. You and your child are being asked to participate in this study because:

1. your child has been diagnosed with asthma;
2. your child is between the ages of 8 and 17 years of age;
3. your child receives medical services in this clinic to care for his or her asthma.

Your participation in this study may not directly benefit you, but will help the researchers to determine ways in which the medical community can improve their strategies for caring for children and adolescents with asthma. You may also help us to identify sources of stress that are unique to families of children with asthma and those that are common to families of children with chronic illness in general.

By signing this form, you are granting permission to the research team to review your child’s pharmacy and medical records to obtain relevant information regarding your child’s asthma. Your participation in this study is voluntary, and consent can be revoked at any time.

If you agree to allow your child’s medical and pharmacy records to be reviewed, please print your name and your child’s name, and sign your name in the appropriate space below.
If you agree to join this study, please sign your name below.

NOT VALID WITHOUT THE
IRB STAMP OF CERTIFICATION

Subject's signature
Date:

I have read and understood the information on this form
I have had the information on this form explained to me.

Date:

Signature of Parent/Legally Appointed Guardian
(When Applicable)
Date:

Signature of Investigator or Authorized
Representative obtaining informed consent
Date:

Witness to Consent procedure
(Optional unless subject is illiterate, or unable to sign)
Date:

Investigator reviewed consent form and is aware of Subject
enrollment.
Date:

*Optional unless subject is illiterate, or unable to sign.

NOTE: Copies of this Consent Form with original signatures must be a) retained on file
by the Principal Investigator, and b) given to the subject. A copy must also be deposited
in the patient’s medical record (if any).
APPENDIX H:

ADOLESCENT ASSENT FORM
RESEARCH ASSENT FORM FOR ADOLESCENTS

Project Title: An Investigation of Variables Related to Treatment in Pediatric Asthma

Principal Investigator: Vicki J. Tepper, Ph.D. (410) 706-6538
Co-Investigators: Kellie McCants, M.A., (410) 578-2619
Mary Beth Bollinger, D.O., (410) 706-2443
Thomas Linscheid, Ph.D. (614) 722-4700

The purpose of this study is to find out whether things that happen in your family affect your asthma. You are being asked to participate in this study because:
1. You have asthma;
2. You are between 8 and 17 years old;
3. You come to clinic to see the doctors and nurses about your asthma.

If you choose to participate in the study, you will be asked to fill out a short packet of questions about your feelings about having asthma and what happens when you have an asthma attack. It should only take you about 10-15 minutes to finish the 2 questionnaires. We will also get information about the medicines you take for your asthma. Your parent or guardian will also be asked to fill out some forms.

The information we collect from you and your parent will not be shared with your doctor, nurse, or anyone else who does not work on the research project. After we have called to get information about your medicine, your name (and your parent/guardian’s name) will be erased from all of the questionnaires.

Your participation in this study is voluntary, so no one will be mad at you or treat you any differently if you choose not to fill out the questionnaires. You are allowed to withdraw from the study at any time, which means that if, at any time, you decide you don’t want to finish filling out the papers given to you, you can stop and give them back.

When you and your parent/guardian finish filling out all of the questionnaires, you will receive $5 worth of McDonald’s or Wendy’s gift certificates. You will also be entered in a contest to win one of two $50 gift certificates from Circuit City or Toys R Us, which will be awarded at the end of the study.

If you agree to be in this study, please write your name in the space below.

133
Research Consent Form

If you agree to join this study, please sign your name below.

NOT VALID WITHOUT THE
IRB STAMP OF CERTIFICATION

Valid from 5/15/82 to 2/28/83

Signature of Parent/Legally Appointed Guardian
(When Applicable)

Signature of Investigator or Authorized
Representative obtaining informed consent

Witness to Consent procedure
(Optional unless subject is illiterate, or unable to sign)

Investigator reviewed consent form and is aware of Subject
enrollment.

*Optional unless subject is illiterate, or unable to sign.

NOTE: Copies of this Consent Form with original signatures must be a) retained on file
by the Principal Investigator, and b) given to the subject. A copy must also be deposited
in the patient's medical record (if any).