

**THE EFFECT OF RISK, SIDE EFFECT, AND BENEFIT COMMUNICATION IN
PEDIATRIC ASTHMA VISITS ON ASTHMA CONTROL MEDICATION
ADHERENCE, CAREGIVER- AND CHILD- REPORTED
PROBLEMS/CONCERNS ABOUT SIDE EFFECTS**

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ABSTRACT

CHRISTOPHER GILLETTE: The Effect of Risk, Side Effect, and Benefit Communication in Pediatric Asthma Visits on Asthma Control Medication Adherence, Caregiver- and Child- Reported Problems/Concerns about Side Effects
(Under the direction of Dr. Betsy Sleath)

A secondary analysis was conducted on child interview, caregiver questionnaire, and transcripts of audiotaped medical visit data collected in North Carolina clinics from 2005-2009. The data includes 35 providers and 295 children with persistent asthma. Qualitative analyses examined the content of control medication side effect, risk, and benefit discussions. Generalized estimating equations were used to predict side effect, risk, and benefit discussions, medication adherence, and concerns about side effects.

Results revealed that 4% of visits included side effect discussions. Side effect discussions were more likely with younger children. Sixteen percent of visits included risk discussions. Risks were more likely to be discussed when children were taking/prescribed an inhaled corticosteroid and during longer visits.

Approximately 47% of visits included benefit discussions. Benefits were more likely to be discussed when: the child was younger; the child was taking/prescribed an inhaled corticosteroid; and adherence was discussed.

Average medication adherence was 85%. Caregivers were more likely to report the child as 80% or more adherent when the: child took more control medications, visit was longer, and the child had seen the provider more. Discussions of medication risks

were not associated with control medication adherence of at least 80%, contrary to our hypothesis.

Approximately 37% of caregivers reported a concern about side effects. Caregivers were more likely to report a concern when the child had seen the provider less. Discussions of risks were not associated with caregivers reporting a problem/concern about side effects, contrary to our hypothesis. Approximately 33% of children reported a concern about side effects. Children were more likely to report a concern about side effects when the: caregiver was not married, child did not take an inhaled corticosteroid, and they saw male providers. Discussions of side effects and benefits were not associated with the child reporting a concern, contrary to the hypotheses.

Study results showed that discussions of medication benefits were more frequent than discussions of side effects and risks, although less than half of visits had benefit discussions. Future research should investigate how to improve communication in these areas.

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TABLE OF CONTENTS

ABSTRACT.....	ii
ACKNOWLEDGEMENTS.....	iv
LIST OF TABLES.....	xii
LIST OF FIGURES.....	xvii
CHAPTER 1: BACKGROUND AND SIGNIFICANCE.....	1
PEDIATRIC ASTHMA OVERVIEW.....	2
RISKS, SIDE EFFECTS, AND BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	8
PATIENT-PROVIDER COMMUNICATION.....	18
CONCEPTUAL MODEL USED IN THIS DISSERTATION.....	31
SPECIFIC AIMS.....	35
CHAPTER 2: METHODS FOR QUANTITATIVE ANALYSIS.....	38
OVERVIEW.....	38
STUDY SETTING.....	38
PATIENT ENROLLMENT AND ELIGIBILITY.....	39
DATA COLLECTION AND VARIABLES.....	39
MEASUREMENT.....	43
SAMPLE SIZE AND STATISTICAL POWER.....	61
MISSING DATA.....	62
DATA ANALYSIS.....	64

ANALYSIS BY AIM.....	68
SPECIFIC AIM 1.....	68
SPECIFIC AIM 2.....	69
SPECIFIC AIM 3.....	71
CHAPTER 3: METHODS FOR QUALITATIVE ANALYSIS (AIM 4).....	73
OVERVIEW.....	73
CONTENT ANALYSIS OF THE MEDICAL VISIT TRANSCRIPTS.....	73
QUESTIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	76
STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	77
QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	79
STATEMENTS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	80
QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	83
STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	84
CHAPTER 4: QUANTITATIVE RESULTS.....	89
CHILDREN WITH ASTHMA AND CAREGIVER CHARACTERISTICS OF TOTAL SAMPLE.....	89
PROVIDER CHARACTERISTICS.....	92
MEDICAL VISIT COMMUNICATION CHARACTERISTICS.....	92
CHARACTERISTICS OF MEDICATIONS DISCUSSED DURING MEDICAL VISITS.....	94

BIVARIATE RESULTS AMONG INDEPENDENT VARIABLES.....	95
BIVARIATE RESULTS AMONG INDEPENDENT VARIABLES AND OUTCOME VARIABLES.....	98
MULTIVARIATE ANALYSES.....	102
COMMUNICATION ABOUT ASTHMA CONTROL MEDICATION SIDE EFFECTS.....	102
COMMUNICATION ABOUT MEDICATION RISKS BY CHILD, CAREGIVER, PROVIDER, MEDICATION, AND OTHER COMMUNICATION CHARACTERISTICS.....	103
COMMUNICATION ABOUT MEDICATION BENEFITS BY CHILD, CAREGIVER, PROVIDER, MEDICATION, AND OTHER COMMUNICATION CHARACTERISTICS.....	105
CAREGIVER-REPORTED ADHERENCE OF AT LEAST 80%.....	107
CAREGIVER-REPORTED PROBLEMS AND CONCERNS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	109
CHILD-REPORTED PROBLEMS/CONCERNS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	111
CHAPTER 5: QUALITATIVE RESULTS.....	113
OVERVIEW.....	113
SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS DISCUSSION CONTENT.....	113
PROVIDER QUESTIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	114
PROVIDER STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	115
CAREGIVER QUESTIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	117
CAREGIVER STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	119

CHILDREN’S QUESTIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	120
CHILDREN’S STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	120
DISCUSSIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS CONCLUSION.....	121
RISKS OF ASTHMA CONTROL MEDICATIONS DISCUSSION CONTENT.....	123
PROVIDER QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	123
PROVIDER STATEMENTS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	124
BOGARDUS DIMENSIONS OF RISK COMMUNICATION.....	128
CAREGIVER QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	129
CAREGIVER STATEMENTS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	130
CHILDREN’S QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	132
CHILDREN’S STATEMENTS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	133
DISCUSSIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS CONCLUSION.....	134
BENEFITS OF ASTHMA CONTROL MEDICATIONS DISCUSSION CONTENT.....	135
PROVIDER QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	135
PROVIDER STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	137

CAREGIVER QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	143
CAREGIVER STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	145
CHILDREN’S QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	148
CHILDREN’S STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	149
DISCUSSIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS CONCLUSION.....	151
CONCLUSION ABOUT CONTENT ANALYSIS OF SIDE EFFECT, RISK, AND BENEFIT DISCUSSIONS.....	152
CHAPTER 6: DISCUSSION.....	153
SUMMARY OF FINDINGS.....	153
DISCUSSIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	153
DISCUSSIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	161
DISCUSSIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	169
CAREGIVER-REPORTED ADHERENCE TO ASTHMA CONTROL MEDICATIONS.....	171
CAREGIVER-REPORTED PROBLEMS AND CONCERNS ABOUT SIDE EFFECTS WITH CHILD’S ASTHMA CONTROL MEDICATIONS.....	174
CHILD-REPORTED PROBLEMS AND CONCERNS ABOUT SIDE EFFECTS FROM ASTHMA CONTROL MEDICATIONS.....	176
IMPLICATIONS.....	179
STUDY LIMITATIONS.....	182

STUDY STRENGTHS.....	184
DIRECTIONS FOR FUTURE RESEARCH.....	184
CONCLUSION.....	191
APPENDIX A: ASTHMA CONTROL MEDICATIONS.....	192
APPENDIX B: SUPPLEMENTAL CODING INSTRUMENT.....	193
APPENDIX C: SUPPLEMENTAL CODING INSTRUMENT CODING RULES.....	197
REFERENCES CITED.....	206

LIST OF TABLES

TABLE 1: LIST OF COMMON ASTHMA RESCUE AND CONTROL MEDICATIONS.....	6
TABLE 2: ASTHMA CONTROL MEDICATION CLASSES AND ASSOCIATED ADVERSE EFFECTS.....	9
TABLE 3: OUTCOME VARIABLES, SOURCE, RANGE.....	44
TABLE 4: COMMUNICATION, MEDICAL VISIT, AND MEDICATION VARIABLES.....	46
TABLE 5: CHILD, CAREGIVER, AND PROVIDER VARIABLES.....	56
TABLE 6: VARIABLES WITH MISSING DATA.....	62
TABLE 7: CATEGORIES OF QUESTIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	76
TABLE 8: CATEGORIES OF STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	77
TABLE 9: CATEGORIES OF QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	79
TABLE 10: CATEGORIES OF STATEMENTS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	80
TABLE 11: CATEGORIES OF QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	83
TABLE 12: CATEGORIES OF STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	85
TABLE 13: CHARACTERISTICS OF CHILDREN WITH ASTHMA IN TOTAL SAMPLE (N=295).....	90
TABLE 14: CHARACTERISTICS OF CAREGIVERS OF CHILDREN WITH ASTHMA IN TOTAL SAMPLE (N=295).....	91

TABLE 15: CHARACTERISTICS OF MEDICAL PROVIDERS (N=35).....	92
TABLE 16: MEDICAL VISIT COMMUNICATION CHARACTERISTICS (N=295).....	93
TABLE 17: MEDICATIONS DISCUSSED DURING MEDICAL VISITS (N=295).....	94
TABLE 18: CORRELATION MATRIX BETWEEN INDEPENDENT VARIABLES.....	96
TABLE 19: CORRELATION MATRIX BETWEEN INDEPENDENT AND OUTCOME VARIABLES.....	100
TABLE 20: GENERALIZED ESTIMATING EQUATION PREDICTING RISK DISCUSSIONS RESULTS (N=255).....	104
TABLE 21: GENERALIZED ESTIMATING EQUATION PREDICTING BENEFIT DISCUSSIONS RESULTS (N=255).....	106
TABLE 22: GENERALIZED ESTIMATING EQUATION PREDICTING CAREGIVER-REPORTED ADHERENCE OF AT LEAST 80% (N=214).....	108
TABLE 23: GENERALIZED ESTIMATING EQUATION PREDICTING CAREGIVER-REPORTED PROBLEMS AND CONCERNS WITH SIDE EFFECTS OF CHILD'S ASTHMA CONTROL MEDICATIONS (N=215).....	110
TABLE 24: GENERALIZED ESTIMATING EQUATION PREDICTING CHILD-REPORTED PROBLEMS AND CONCERNS WITH SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS (N=240).....	112
TABLE 25: PERCENTAGE OF VISITS WHERE PROVIDERS ASKED QUESTIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS (N=295).....	115
TABLE 26: ACTUAL PROVIDER QUESTIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	115

TABLE 27: PERCENTAGE OF VISITS WHERE PROVIDERS MADE STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS (N=295).....	116
TABLE 28: ACTUAL PROVIDER STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	116
TABLE 29: PERCENTAGE OF VISITS WHERE CAREGIVERS ASKED QUESTIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS (N=295).....	118
TABLE 30: ACTUAL CAREGIVER QUESTIONS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	118
TABLE 31: PERCENTAGE OF VISITS WHERE CAREGIVERS MADE STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS (N=295).....	119
TABLE 32: ACTUAL CAREGIVER STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	120
TABLE 33: PERCENTAGE OF VISITS WHERE CHILDREN MADE STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS (N=295).....	121
TABLE 34: ACTUAL CHILD STATEMENTS ABOUT SIDE EFFECTS OF ASTHMA CONTROL MEDICATIONS.....	121
TABLE 35: PERCENTAGES OF VISITS OF PROVIDER QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS (N=295).....	123
TABLE 36: ACTUAL PROVIDER QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	124
TABLE 37: PERCENTAGES OF VISITS OF PROVIDER STATEMENTS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS (N=295).....	124
TABLE 38: ACTUAL PROVIDER STATEMENTS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	126

TABLE 39: BOGARDUS DIMENSIONS OF RISKS DISCUSSED IN MEDICAL VISITS.....	128
TABLE 40: PERCENTAGE OF VISITS OF CAREGIVER QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS (N=295).....	129
TABLE 41: ACTUAL CAREGIVER QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	130
TABLE 42: PERCENTAGE OF VISITS OF CAREGIVER STATEMENTS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS (N=295).....	131
TABLE 43: ACTUAL CAREGIVER STATEMENTS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	132
TABLE 44: PERCENTAGE OF VISITS OF CHILD QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS (N=295).....	133
TABLE 45: ACTUAL CHILD QUESTIONS ABOUT RISKS OF ASTHMA CONTROL MEDICATIONS.....	133
TABLE 46: PERCENTAGE OF VISITS OF PROVIDER QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS (N=295).....	136
TABLE 47: ACTUAL PROVIDER QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	137
TABLE 48: PERCENTAGE OF VISITS OF PROVIDER STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS (N=295).....	138
TABLE 49: ACTUAL PROVIDER STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	139
TABLE 50: PERCENTAGE OF VISITS OF CAREGIVER QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS (N=295).....	144

TABLE 51: ACTUAL CAREGIVER QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	144
TABLE 52: PERCENTAGE OF VISITS OF CAREGIVER STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS (N=295).....	145
TABLE 53: ACTUAL CAREGIVER STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	147
TABLE 54: PERCENTAGE OF VISITS OF CHILD QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS (N=295).....	148
TABLE 55: ACTUAL CHILD QUESTIONS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	148
TABLE 56: PERCENTAGE OF VISITS OF CHILD STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS (N=295).....	149
TABLE 57: ACTUAL CHILD STATEMENTS ABOUT BENEFITS OF ASTHMA CONTROL MEDICATIONS.....	150

LIST OF FIGURES

FIGURE 1: FRAMEWORK USED IN CODING COMMUNICATION.....	30
FIGURE 2: CONCEPTUAL MODEL LINKING CHARACTERISTICS TO COMMUNICATION AND OUTCOMES.....	32

CHAPTER ONE: BACKGROUND AND SIGNIFICANCE

Overview and Organization

The background and rationale for this project is presented in this chapter and is organized into four sections: (1) Pediatric Asthma Overview; (2) Risks, Side Effects, and Benefits of Asthma Control Medications; (3) Patient-Provider Communication; and (4) Conceptual Framework.

The Pediatric Asthma Overview section provides a brief overview of asthma in children in the United States, including prevalence and outcomes, as well as introducing select topics from the national guidelines for the treatment of asthma that have been developed by the National Asthma Education and Prevention Program (NAEPP)[NAEPP, 2007]. The Risks, Side Effects, and Benefits of Asthma Control Medications section outlines the role and importance of these medications in controlling the disease. This section also outlines the potential risks and benefits that are associated with these medications, in addition to summarizing the literature on both adherence to asthma control medications and child- and caregiver-reported problems and concerns with side effects. The Patient-Provider Communication section provides an overview of the importance of good communication between the patient and provider, including some of the recommendations provided by the NAEPP (NAEPP, 2007). This section also outlines previous research on risk communication between patients and providers. Finally, the Conceptual Framework section presents the framework that was used to explore the

relationship between communication of risks, side effects, and benefits of asthma control medications, adherence to asthma control medications, and caregiver- and child-stated problems and concerns with side effects of asthma control medications.

Pediatric Asthma Overview

Introduction

Asthma is a chronic disease, affecting more than nine million children in the United States (Butz, et. al. 2007). Asthma is characterized by inflammation and constriction of the airways, leading to breathing difficulties. Since 1980 through the late 1990s, asthma prevalence more than doubled (Akinbami 2006). Since the late 1990s the prevalence of asthma has been relatively stable in the United States. However, since the plateau of asthma prevalence, ambulatory care use has continued to grow (Akinbami 2006).

Health Outcomes and Healthcare Utilization

Children diagnosed with asthma are likely to experience symptoms that negatively affect daily living. The symptoms experienced may include: (a) wheezing, (b) coughing, (c) shortness of breath, or (d) chest pain/tightness. The onset of symptoms can lead to limited daily functioning, decreased quality of life, missed school days, non-participation in physical activities, as well as negatively affecting caregiver work attendance and productivity (Diette et. al. 2000, et. al., Schmier et. al. 2007). In 2004, asthma accounted for seven million outpatient visits for children. Every year, pediatric asthma is responsible for 658,000 to 754,000 emergency department visits and almost 200,000 hospitalizations (Coffman et. al. 2008). The morbidity associated with asthma has a

greater impact than mortality although some people can suffer life-threatening asthma episodes.

This increase in healthcare utilization leads to increased costs and lost wages for parents. Using data collected from the Medical Expenditures Panel Survey (MEPS) from 1996 and converted into 2003 dollars, direct costs for asthma accounted for over \$1 billion (\$401 per each child with asthma), which included payments for prescription medications, hospital inpatient stays, hospital outpatient visits, emergency department visits, and office – based visits (Wang et. al. 2005). In addition to direct costs, asthma has significant indirect costs associated with it. For example, in children, asthma is one of the leading causes of school absenteeism, accounting for 10 – 15 million missed school days each year (Wang et. al. 2005). Children with asthma miss 1.5 – 2 more school days per year than children without asthma. Asthma also affects quality of life for the child and the entire family, due to missed time from work for parents and inability to exercise and play for the asthmatic child (Wang et. al. 2005, Diette et. al. 2000, Schmier et. al. 2007). Finally, parent lost productivity from asthma-related school absences is approximately \$719.1 million (Wang et. al. 2005). The total economic impact of childhood asthma is almost \$2 billion in the United States alone (Wang et. al., 2005).

National Guidelines

National guidelines or clinical practice guidelines are developed to assist the practitioner in providing optimal care based on available evidence (NAEPP 2007). An expert panel commissioned by the National Asthma Education and Prevention Program Coordinating

Committee, coordinated by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH), have developed Guidelines for the Diagnosis and Management of Asthma. The Guidelines are now in their third edition (Expert Panel Report 3 or EPR-3), which was published in 2007. Because the parent grant, upon which this dissertation is based, began prior to the EPR-3, this dissertation will reference the EPR-2 (NAEPP, 1997). EPR-2 was developed prior to the parent grant and was the most current when data collection began for the parent grant. Therefore, all references are to the EPR-2, unless otherwise noted. The changes from the EPR-2 to the EPR-3 focus on different aspects of asthma diagnosis and management. For example, the EPR-3 places a new emphasis on using FEV1/FVC in classifying severity in children because it may be a more sensitive measure than only FEV1 (NAEPP, 2007). The EPR-3 guidelines also present information on new medications. However, the communication recommendations were stable from EPR-2 to EPR-3.

The NAEPP guidelines support four central tenets for managing long-term asthma and exacerbations: (1) assessment and monitoring, (2) patient education, (3) control of factors leading to asthma severity, and (4) pharmacologic treatment. The guidelines provide comprehensive asthma management and treatment recommendations (NAEPP, 2007). Only those aspects that relate directly to this dissertation will be referenced.

Disease Severity Classifications

The 2007 guidelines classify asthma into four different severity levels that are based on several factors, including: symptoms, nighttime awakenings, short-acting beta agonist

use, and lung function. The four severity classifications in order of increasing severity are: (1) intermittent, (2) mild persistent, (3) moderate persistent, and (4) severe persistent.

Intermittent asthma is defined by the NAEPP as infrequent exacerbations separated by periods of no symptoms and normal pulmonary function. This is defined as: (a) asthma symptoms occurring less than two days per week, or (b) less than 2 night awakenings from asthma symptoms per month, or (c) using a short-acting beta-agonist less than two days per week. Mild persistent asthma is defined as: (a) asthma symptoms occurring more than two days per week but not daily, or (b) three to four nighttime awakenings from asthma symptoms per month, or (c) using a short-acting beta-agonist more than two days per week but not daily. Moderate/severe persistent asthma is defined as: (a) daily asthma symptoms, (b) more than one nighttime awakening per week but not nightly, or (c) daily use of a short-acting beta-agonist. Severe persistent asthma consists of: (a) symptoms occurring throughout the day, (b) being awakened by asthma symptoms often seven nights per week, or (c) using a short-acting beta-agonist several times through the day (NAEPP 2007).

Medications

Despite the fact that there is no known cure for asthma at the present time, asthma can be controlled with the proper use of medications. The goal of pharmacologic treatment of asthma is to control symptoms and reduce exacerbations. There are two main categories of medications that are used to treat asthma: “rescue” medications and “control” medications (NAEPP 2007). “Rescue” medications are short-acting medications that are

used for acute exacerbations of symptoms, which include coughing, wheezing, shortness of breath, and chest pain/tightness. These “rescue” medications come from three classes, short-acting beta-agonists, anticholinergics, and systemic corticosteroids. “Control” medications are used to maintain control of persistent asthma symptoms. “Control” medications prevent or control inflammation or bronchospasms. The classes of control medications are: (a) inhaled corticosteroids (ICS), (b) cromolyn sodium and nedocromil, (c) immunomodulators, (d) systemic corticosteroids, (e) leukotriene receptor antagonists (LTRAs), (f) 5-lipoxygenase inhibitor, (g) long-acting beta-agonists, and (h) methylxanthines. **Table 1** below lists the more common asthma “rescue” and control medications, compiled from the national guidelines and the medication list from the parent grant. The table lists the generic name, the medication class, type, and brand name for each medication.

Table 1: List of Common Asthma Rescue and Control Medications

Class		
"Rescue" Medications	Generic Name	Brand Name(s)
<i>Short Acting Beta Agonists</i>	Albuterol	Proventil, Ventolin
	Pirbuterol	Maxair
	Levalbuterol	Xopenex
<i>Anticholinergics</i>	Ipratropium	Atrovent
	Albuterol/Ipratropium	Combivent
Control Medications		
<i>Inhaled Corticosteroids</i>	Beclomethasone	Qvar
	Fluticasone	Flovent
	Budesonide	Pulmicort
	Mometasone	Asmanex
<i>Leukotriene Modifiers</i>	Montelukast	Singulair
<i>Long Acting Beta Agonists</i>	Salmeterol	Serevent
	Formoterol	Foradil
<i>Inhaled Corticosteroids & Long Acting Beta Agonists</i>	Budesonide/Formoterol	Symbicort
	Fluticasone/Salmeterol	Advair

The NAEPP guidelines and the National Heart, Lung, and Blood Institute state that all people with persistent asthma should be treated with a daily control medication to achieve and maintain asthma control.

NAEPP Guidelines Concerning Communication of Risks, Side Effects, and Benefits

The guidelines address what medical providers should assess during a routine clinic visit. Medical providers should monitor pharmacotherapy by asking about specific side effects the patient may have experienced from any their daily medications. Furthermore, the guidelines instruct medical providers to teach and reinforce the roles of short-acting beta-agonists and long-term control medications at every opportunity. This strategy aims to educate patients and their caregivers about the benefits of both “rescue” medications and long-term control medications. Finally, the guidelines encourage open communication to ensure patient satisfaction and greater adherence to therapy. This open communication should include having patients and caregivers weigh the risks and benefits of medications so that the provider addresses fears and concerns about medications. Allaying the fears and concerns about the medications could potentially improve adherence, which should enhance patient outcomes.

Summary

In conclusion, asthma is a common and costly problem in the United States. For the children who are affected by asthma, consequences of the disease may include lost time from school, not being able to play/exercise with friends, numerous outpatient visits, lost

time from work for parents, and in the most extreme cases, death (Wang et. al. 2005). The NHBLI continually updates national guidelines to assist medical providers in the diagnosis and management of asthma (NAEPP 2007). For persistent asthma, control medications are used to increase quality of life and prevent symptoms. The risks, side effects, and benefits of asthma control medications will be discussed in greater detail below.

Risks, Side Effects, and Benefits of Asthma Control Medications

Introduction

This section will explain the adverse effects associated with regular use of asthma control medications. Additionally, this section will explain the benefits of regular use of asthma control medications. For the purposes of this dissertation, risks were defined as potential adverse reactions that could occur as a result of using a medication, but have not yet been experienced by a patient using that medication. Also, adverse effects that were discussed for medications the child had not yet taken were also defined as risks. An example of a risk as defined in this dissertation would be the possible risk of stunted growth from inhaled corticosteroid (ICS) medications. Side effects were defined as adverse reactions that the patient was experiencing on the day of the visit or had experienced prior to the audio taped visit. An example of a side effect as defined in this dissertation would be oral thrush being experienced by the patient at the visit or sometime prior to the visit, since the patient's susceptibility to experiencing the side effect is known. Benefits were defined as positive outcomes, both potential and presently being experienced, that result

from using the medication. An example of a benefit of an ICS medication is the decreased need for short-acting beta-agonist medications.

Risks Related to Asthma Control Medications

Local and systemic adverse effects have been identified with use of asthma control medications, especially ICS medications and long-acting beta-agonists (LABA). **Table 2** lists the medication classes and potential adverse effects. Systemic corticosteroids are included in this list, but can also be used as short-term “burst” therapy to gain prompt control of inadequately controlled persistent asthma. (NAEPP, 2007). This section will address the most pertinent risks that have been associated with asthma control medications, with a focus on risks associated with ICS and LABA medications. Some risks of control medications may only apply to adults or geriatric patients (e.g. osteoporosis) or medications that are not commonly used for asthma control (e.g. cromolyn sodium, immunomodulators, and Zafirlukast).

Table 2: Asthma Control Medication Classes and Associated Adverse Effects

Long-Term Asthma Control Medications and Potential Adverse Effects	
Class Name	Potential Adverse Effects
Inhaled Corticosteroids	Cough
	Dysphonia
	Oral thrush
	In low to medium doses in children, growth suppression but may be transient
	In high doses: Adrenal suppression
	Osteoporosis
	Skin thinning
	Easy bruising

Class Name	Potential Adverse Effects
Systemic Corticosteroids	Short-term use: Reversible abnormalities in glucose metabolism
	Increased appetite
	Fluid retention
	Weight gain
	Mood alteration
	Hypertension
	Peptic ulcer
	Rarely aseptic necrosis
Mast cell stabilizer	Cough
	Irritation
	15-20% of patients report unpleasant taste
Immunomodulators	Pain and bruising at injection sites
	Anaphylaxis
Leukotriene Receptor Antagonists	With Zafirlukast: Reversible hepatitis
	Irreversible hepatic failure
	Death
Long-Acting Beta Agonists	Diminished bronchoprotective effect may occur within 1 week of initiating therapy
	Tachycardia
	Skeletal muscle tremor
	Hypokalemia
	Prolongation of QTc interval in overdose
	Uncommon severe, life-threatening or fatal exacerbation
Methylxanthenes	Insomnia
	Gastric upset
	Aggravation of ulcer or reflux
	Increase in hyperactivity of children

- Local Adverse Effects of ICS

One of the most common adverse effects of ICSs is oral candidiasis or thrush. Thrush is more common in adults than children. There are prevention recommendations in addition to treatment recommendations for thrush (NAEPP 2007). Dysphonia is another local adverse effect and can be prevented and treated as well (NAEPP 2007). Reflex cough and bronchospasm are other local adverse effects (AE) that have been identified by the NAEPP guidelines (NAEPP, 2007). Treatment and prevention is available for this local AE as well.

- Systemic Adverse Effects of ICS

The most pertinent systemic adverse effect of ICS medications is a reduction in linear growth and growth velocity for children (NAEPP 2007). Research on ICSs effect on growth has shown that ICSs may impede growth velocity, but the effects are small and may be reversible (NAEPP 2007, Skoner, 2002). For example, one study in Sweden found that ICS medications had no impact on final adult height (Norjavaara E. et. al. 2000). However, that study did find that asthma severity was a major determinant of final adult height (Norjavaara et. al., 2000). Since poorly controlled asthma may be a significant factor in final adult height and ICSs have not been shown to significantly reduce height, the benefits of ICSs outweigh the risks of reduced height (NAEPP 2007, Skoner 2002). Other adverse effects that are thought not to be clinically significant in children are: (a) decreased bone mineral density, (b) glaucoma and cataracts, (c) impaired glucose metabolism, and (d) weakened hypothalamic pituitary adrenal axis function (NAEPP 2007).

- Risks of Long-Acting Beta-Agonists (LABAs)

The NAEPP guidelines also address the risks of long-acting beta-agonist (LABA) medications (NAEPP 2007). This class of medication is thought to increase the chances of asthma-related deaths and the FDA label for products containing LABA medications includes a ‘black box’ warning. The guidelines recommend that LABAs be adjunctive therapy for those whose asthma is not well controlled with ICS alone (NAEPP 2007).

The increased potential for asthma related deaths has resulted in LABAs not being recommended as monotherapy for asthma (NAEPP 2007). The guidelines go on to state that the decision to increase the dose of ICS should be given equal weight to the addition of LABA medications. Studies have shown that those who discontinue ICS after the addition of LABA may face the greatest risk of asthma-related death because LABAs do not treat inflammation, although they maintain lung function, which may cause patients to delay seeking treatment (NAEPP 2007).

Other medications and medication classes that are used as long-term control therapy include: (a) mast cell stabilizers, (b) immunomodulators, (c) leukotriene receptor antagonists, (d) long-acting beta agonists, and (e) methylxanthenes. Though the majority of identified adverse reactions for asthma control medications belong to the ICS and LABA classes, other medications that are used for long-term control of asthma have potential adverse effects as well.

Caregiver and Child Perceptions of Risks and Side Effects of Control Medications

Previous studies have shown that caregivers of children with asthma have concerns about daily use of a control medication (Sleath et. al. 2010, Smith et. al. 2008, Conn et. al. 2007, Conn et. al. 2005). In two different samples, Conn found that 34% and 30% respectively, of caregivers reported strong concerns in using asthma control medications (Conn et. al. 2007, Conn et. al. 2005). Concerns that were identified included concerns about dependency and adverse effects. Furthermore, 17% of caregivers reported that concerns about their child's medications exceeded the necessity scores. Caregivers who scored higher on concerns about control medications were found to be more likely to under-use asthma control medications (Smith et. al. 2008). Sleath et. al. found that 31% of caregivers reported that side effects bothered their child a little or a lot (Sleath et. al. 2010). These studies collectively show that strong concerns about taking a daily medication for asthma may result in suboptimal adherence of control medications. This dissertation is unique because it is the first study to assess the relationship between discussions about adverse effects (side effects and risks) and medication benefits and child- and caregiver-reported problems and concerns about adverse effects.

Prior studies have found that asthmatic children also have concerns about using a control medication (Sleath et. al. 2010, Logan et. al. 2003). Sleath and colleagues found that 87% of children with persistent asthma cited at least one problem/concern in using asthma medications (Sleath et. al. 2010). That same study also found that 40% of children cited side effects as a problem/concern. Logan et. al. (2003) developed a scale with five factors for illness management for children with asthma. The scale identifies

five domains as barriers, including medication regimen concerns and problems. The scale was shown to correlate with self-reported medication adherence. Problems and concerns that children reported with medications included: (1) regimen causes changes to my body that I don't like, (2) doctors don't understand how much the regimen impacts important things in life, (3) the regimen has side effects that I don't like, and (4) following the regimen causes physical pain and discomfort.

Naimi et. al. found that 45% of children did not like the taste of fluticasone/salmeterol but few reported that the taste of the medication discouraged them from using the medication. Other concerns that teenagers had of asthma control medications were: fear of addiction, the medication gave them acne, or made them "stocky" (Naimi et. al. 2009). Further, Penza-Clyve et. al. found that children state their asthma control medications taste bad and they have concerns about adverse effects, such as becoming hyperactive, which may decrease children's adherence to these medications (Penza-Clyve et. al. 2004).

Benefits of Asthma Control Medications

All asthma control medications were developed to: (a) reduce symptoms, (b) improve asthma control, (c) improve quality of life, (d) prevent exacerbations, and (e) reduce the need for systemic corticosteroids, emergency department usage, and death due to asthma (NAEPP 2007). The NAEPP states that ICSs are the most potent and most consistently effective asthma control medications available (NAEPP 2007). ICSs are characterized by their anti-inflammatory activity, which may account for their efficacy in controlling

asthma. The NAEPP also recommends ICSs over all other asthma control medications, including leukotriene receptor antagonists (LTRAs) (NAEPP 2007). Those patients who are not well controlled on one asthma control medication may need adjunctive therapy. More specifically, adjunctive therapy is a combination of an ICS and LABA. However, adjunctive therapy has not been well studied in children 5-11 years of age. The research supports the use of adjunctive therapy in older children rather than increasing the dosage of an ICS or adding an LTRA (NAEPP, 2007).

Non-Adherence to Asthma Control Medications

Despite the availability of effective asthma control medications, non-adherence is a significant problem. Studies have found that children only take approximately 50% of their regularly prescribed asthma medications (McQuaid et. al. 2003, Bender et. al. 1998, Penza-Clyve et. al. 2004, Jones et. al. 2003). Adherence has been shown to be related to: (a) age (older age is associated with poorer adherence), (b) route of administration (children taking tablets are more adherent than those using metered-dose inhalers), (c) regimen complexity (more medications result in poorer adherence), (d) minority status (minorities are less adherent), and (e) side effects (McQuaid et. al. 2003, Modi and Quittner 2006, Rau 2005, Chambers et. al. 2001). Research has shown that effective communication between providers and patients may be an area that can significantly improve medication adherence in asthma, highlighting the importance of this dissertation (Rau 2005). In one study of adherence in children with asthma by Kyngas and Rissanen, there was a correlation between medication adherence and perceived support from physicians. Perceived support is evidenced by encouragement and positive feedback,

aspects of communication that may positively impact asthma medication adherence (Kyngas and Rissanen 2001).

According to prior research, the general population is concerned about the safety of long-term asthma control medications, which may predict poor adherence (Conn et. al. 2005, Conn et. al. 2007, Smith et. al. 2008, Le et. al. 2008, Choi et. al. 2008). In a study of adults with asthma, patients who reported themselves as accepting and ambivalent about control medications had significantly higher adherence than those who were indifferent and skeptical about the need for preventer medications (Menckeberg et. al. 2008). Chambers et. al. (2001) recruited adults into a study that assessed their attitudes about regular use of ICS and found that fear of side effects was the most frequently cited reason for nonadherence. Wroe (2002) found that intentional nonadherence (missing doses to suit one's needs) was predicted by the individual's weighing of the pros and cons for themselves based on the information they have at hand. These findings suggest that an individual's concerns about a medication may lead him/her to intentionally miss doses based on the information they can access. However, providers are in an ideal position to communicate effectively about the nature and course of the disease to both children and their primary caregivers during a medical visit. This communication can be used to educate both children and their caregivers so that adherence to these medications can be improved.

Child and Caregiver Reported Problems and Concerns with Asthma Medications

There has been little research to determine the types of problems and concerns that children and their caregivers may have about asthma medications. Only one paper has studied the problems that children report with their asthma medications (Sleath et. al. 2010). Approximately 40% of children reported a problem/concern with side effects of their asthma medication(s) and approximately 31% of caregivers reported that children were bothered a little or a lot by side effects. Providers are in a crucial position to ask children and caregivers about problems/concerns with asthma medications during a medical visit and then educate and alleviate those concerns. Alleviating concerns about side effects could result in better asthma control medication adherence in children.

Other prior research has found that minorities tend to have lower asthma medication adherence than Caucasians. Minorities also are more likely to have negative beliefs concerning asthma control medications. Le and colleagues (2008) found that minorities were significantly more likely to hold more negative beliefs about asthma medication and also found that negative beliefs were associated with significantly lower adherence. Beliefs that Le (2008) cited included: (a) “using an inhaled steroid every day may cause long-term side effects and problems”, (b) “I don’t like the idea of using an inhaled steroid medicine,” and (c) “if I use my inhaled steroid every day it won’t work as well when I need it” (Le et. al. 2008).

Further, communication in pediatrics has been shown to have a stronger relationship with adherence than in adults (Drotar and Bonner 2009). The exact mechanism is unclear for

this stronger effect size in pediatrics. This dissertation has the potential to inform future work in pediatric communication research by increasing understanding of how providers talk to children and their caregivers about the risks, side effects, and benefits of asthma control medications and the relationship between communication and asthma control medication adherence. This dissertation also will examine the communication about risks, side effects, and benefits in-depth and how this communication impacts child and caregiver reported problems of side effects with their asthma medications.

Summary

Almost all long-term asthma control medications have potential risks associated with regular use and therefore it is important to understand how providers discuss the risks associated with daily treatment. Caregivers and children alike report concerns and fears about side effects of their asthma control medications. Prior research has found that caregivers and children may purposefully decrease their use of an asthma control medication because of concerns about adverse effects.

Provider-Patient Communication

Introduction

Effective communication between providers and patients is associated with positive health outcomes, such as improved medication adherence (Janson et. al. 2003, Street et. al. 2008). However, it is unknown through which explanatory mechanisms or why elements of provider-caregiver-child communication are associated with better health outcomes (Street et. al. 2008). Provider-patient communication research about

medications has focused on many aspects, including: (a) shared decision making in depression (Young et. al. 2006), (b) discussion of costs of medications with rheumatoid arthritis patients (Beard et. al. 2010), (c) information providers give patients when prescribing antidepressants (Young et. al. 2008), and (d) discussions of complementary and alternative medicine with rheumatoid arthritis patients (Sleath et. al. 2008). The objective of this study was to explore if communication about the risks, side effects, and benefits of asthma control medications is associated with adherence to these medications and determine if there is a relationship between this communication and reported concerns and problems with side effects of asthma control medications. To our knowledge, no prior study has examined the relationship between the communication of risks, side effects, and benefits on asthma control medication adherence as well as child- and caregiver-reported problems and concerns about side effects of asthma control medications.

Children's Participation in Medical Visits

Past research supports the notion that school-age children can participate in self-management decisions and that they are accurate reporters of their asthma symptoms and health status (Butz et. al. 2007). However, past research has found that providers speak little to children and that children are not often engaged in the medical visit (Butz et. al. 2007, Wissow et. al. 1998). Prior research has found that both caregivers and providers may, intentionally or not, restrict the child's participation in a medical visit. Caregivers are likely to speak for a child and providers tend to align with the caregiver through the course of the interaction (Tates et. al. 2002). Prior research has also found that parents

often interfere when providers interact with the child in medical visits, and that children may not be socialized enough to participate in a medical visit (Tates et. al. 2002). This deficit in socialization during a medical encounter has important implications. However, increasing international attention has been paid to the ability of a child taking an active role in their own health care (Ulph et. al., 2009). Therefore, this study is significant because it is the first to describe how children are participating in discussions of asthma medication risks and benefits with their medical providers and caregivers. Given that improved health outcomes, such as medication adherence, can be positively influenced by provider-caregiver-children communication, this study was significant.

Risk Communication and Medications

Risk communication is a national research priority for the Food and Drug Administration. A 2006 report from the Institute of Medicine criticized the FDA because of drug withdrawals due to safety concerns (IOM 2006). In response, the FDA established the Risk Communication Advisory Committee to investigate how to more effectively communicate the risks associated with medications.

Approximately half of the patients in North America, Europe, and Japan fail to take their medications properly (Thurmann 2006). One of the largest deficits in patient understanding is awareness and comprehension of the risks associated with medications (Vogt, 2002 and Thurman, 2006). Thus, providers play a crucial role in helping both patients and their caregivers understand the risks that are associated with medications in treating persistent asthma. However, Thurmann (2006) describes risk communication as

a two-way conversation, not just an explanation by the provider to the patient. Further, research has shown that most patients are not well informed about the side effects of their medication and that 50-90% would like more information (Thurmann 2006). Zeigler et. al. (2001) found that more than 76% of patients wanted to hear all adverse effects of their medications, no matter how rare. Interestingly, those with higher education and younger age desired less information about adverse effects (Zeigler, 2001).

Important Aspects of Risk Communication

Medical practice is moving towards a patient-centered model of care. However, research has shown that children participate very little during the clinic visit (Butz et. al. 2007, Wissow et. al. 1998). Risk communication is multi-faceted and research in risk communication is currently in its infancy. The FDA has focused particular attention to how providers communicate the inherent risks that are associated with medical treatment by instituting a risk communication advisory committee to reflect the FDA's commitment to better understand risk communication. Further, research has shown that people desire information about the potential adverse effects of their medications (Thurmann 2006).

There are a number of frameworks that reflect basic dimensions of risk that should be addressed in a medical visit (Reyna and Brainerd 1995, Bogardus et. al. 1999, Makoul and Clayman 2006), but there is currently no consensus on how to communicate those risks. However, prior research has shown that the way in which providers frame the presentation of risk (verbal, numerical, graphical, one-on-one, etc.) has a significant effect on patient's perception of risk (Edwards et. al. 2000, Zikmund-Fisher et. al. 2008).

Therefore, the current study is innovative because it was the first to describe how providers communicate risks of asthma control medications to children and their primary caregivers by coding specifically for two aspects of how providers discuss the probability of a risk occurring: (1) qualitatively and (2) numerically. A qualitative statement of the probability of a risk occurring uses words such as: likely, not likely, rare, etc. to convey the chances of a risk occurring while a numerical statement uses numbers or percentages such as 1% chance of Risk A occurring. Bogardus' framework (1999) and Makoul et. al.'s Shared Decision Making framework (2006) was used to guide this study. Bogardus' framework (1999) was designed to give providers a basic framework for how to discuss medication and medical procedure risks (such as surgery). Makoul and colleagues' framework (2006) was developed to define essential discussions that needed to be discussed between providers and patients for shared decision making to occur. Specifically, Bogardus' (1999) framework was used in its entirety while Makoul et. al.'s SDM framework (2006) was narrowed down to the discussion of benefits and risks aspect that is essential for SDM to actually occur in medical treatment. The two frameworks that were used in this dissertation will now be discussed in more detail.

One framework that can be useful in researching communication of risk is the framework developed by Bogardus et. al (Bogardus 1999). This framework was developed specifically to provide medical providers with the most basic way to discuss the adverse risks associated with any medical action the physician may take. The framework is separated into five basic dimensions that the provider should discuss with the patient before any medical action is undertaken, such as discussing the risks associated with a

medication. The five dimensions are: (1) identity, (2) permanence, (3) timing, (4) probability, and (5) value. A brief description of each dimension follows.

The first dimension that Bogardus addresses is identity. This dimension involves identifying the pertinent unwanted outcomes for the medical action. The second dimension is permanence, or how long the risk will affect the patient. Providers should discuss this issue with patients and their caregivers so that children and their caregivers could have a different outlook about their asthma medications. The third dimension is timing, or when is the risk likely to occur. The fourth dimension of risk communication is probability, or how likely the unwanted outcome will occur. Lastly, the final dimension is the value that the patient places on the risk. This is defined as the level of importance the patient places on the risk for himself/herself or a child in their care. Bogardus states that providers should ask children and caregivers about concerns and values regarding the adverse effects of using medications.

A second framework that is useful in risk communication research is the theory of shared decision-making (SDM) (Makoul et. al. 2006). SDM is defined as the provider and patient interacting and sharing their thoughts and feelings regarding a medical event. There are many essential aspects of SDM that Makoul addresses (2006), but the element about risk/benefit communication is the most pertinent to this dissertation. Makoul et. al. (2006) identified several elements they considered to be essential for SDM to occur. They defined these essential elements as basic topics that needed to be discussed in order for SDM to have occurred in an office visit. Risk/benefit communication was defined as

an essential element of SDM by Makoul et. al. (Makoul et. al. 2006). Providers should discuss different options, if they exist, with patients as well as the pros and cons of each option. This discussion then would flow easily with patient values and preferences regarding treatment. The discussion of pros and cons then should reflect higher patient knowledge about their treatment and lead to less concern about medications.

How providers choose to discuss probability of a risk is directly mentioned by Bogardus (1999) and Makoul et. al. (2006) as important in a discussion of risks of a course of action. Bogardus' (1999) framework states that providers should discuss the probability of a risk occurring while Makoul et. al.'s framework (2006) states that providers should discuss the benefits and risks of a course of action in order for true shared decision making to occur. Discussing not only what a risk is but also its chance of occurring is essential for both patients and providers in choosing the most appropriate treatment option.

Conveying Risk Probability: Qualitatively

One of the key issues in conveying risk information to children and adults is the concept of how well they understand probabilistic information. The ability of children and adults to correctly understand probabilistic information will allow them to make better and more informed decisions about their own health care. However, past and present research has failed to come up with a "gold standard" way of communicating probabilistic information (Bogardus 1999).

One way to convey probabilistic information about the risks of medications is presenting probability in a qualitative fashion. Conveying probabilistic information this way has the advantage of using common words to describe the likelihood of certain events occurring (Lipkus 2007). An example of qualitatively describing probabilities is: “One common side effect of using an inhaled corticosteroid is oral thrush.” A disadvantage of using qualitative terms to describe risk is that there is no specific anchoring point for all people and words can be taken to convey different meanings from person to person (Vischers et. al. 2008, Lipkus 2007). A prior study found that in over 73% of medical visits, family providers used qualitative ways of presenting probabilistic information, which was the most often used form of presenting risk information (Neuner-Jehle et. al. 2011).

However, patient understanding was significantly higher in this study when the provider used visual aids (i.e. graphs) to communicate probabilistic information compared to qualitative methods of presenting risk information (Neuner-Jehle et. al. 2011).

There are differences among medical providers and patients in how they would like risk information. For example in one study, physicians preferred to use qualitative expressions of risk information while the general public found that numerical expressions of risk (e.g. 1% of side effect A occurring) were more helpful (Nelson et. al. 2008).

As stated above, people desire probability information to be presented in different ways. For example, some prefer using only words to describe the likelihood of an event while some prefer the information to be presented using only numbers while others prefer a mix of words and numbers (Mazur and Hickam, 1991). Research has shown that the severity

of the expected outcome, older age, and the scale of the probabilities (i.e. <1 out of 1,000,000 vs. <1 out of 1,000) influence interpretations of verbal/qualitative risk terms, with older patients providing significantly higher estimations of a risk occurring than younger patients and the “rare” risk of death being rated as less likely than the “rare” risk of severe pneumonia (Mazur and Merz 1994).

In 2006, the European Union issued guidelines concerning recommended descriptors for frequency of adverse drug reactions (Thurmann 2006). These descriptors along with the probabilities that define each descriptor are: (a) very common = >10%; (b) common = 1-10%; (c) uncommon = 0.1-1%; (d) rare = 0.01-0.1%; and (e) very rare = <0.01%.

(Thurmann 2006). However, research has consistently reported that people tend to grossly over-estimate the probability of a risk occurring when qualitative expressions are used (Thurmann 2006, Knapp et. al. 2009, Knapp et. al. 2004, Berry et. al. 2002, Berry et. al. 2003).

Conveying Risk Probability: Numerically

Another way to present risk likelihood is using numbers, such as frequencies and percentages. A disadvantage of using numbers to convey such information is that many people lack numerical skills (Fagerlin et. al. 2005). The advantage of using numbers to present risk probability is that many people have been found to be more accurate with their estimate of that risk (Waldron et. al. 2010, Knapp et. al. 2009, Berry et. al. 2002, Berry et. al. 2003).

Numeracy and Risk Communication

Numerous studies have shown that many people lack skills to sufficiently understand numbers (numeracy) (Fagerlin, et. al. 2005). Prior research has found that those with low numeracy are more likely to have negative outcomes associated with treatment, especially when that treatment is complicated (Estrada et. al. 2004). However, because medical care is shifting towards shared decision-making, patients are more often asked to be involved in their own medical care. This is especially evident in young children, who may also lack the numerical skills to understand probabilities. Further, prior research has shown that those with low numeracy significantly over-estimated their risk of developing a disease while those with higher numeracy were more accurate (Fagerlin et. al. 2005). Zeigler also commented that those with low numeracy may be more willing to hear all adverse effects no matter how rare because they are uncomfortable dealing with numbers (Zeigler et. al. 2001).

Research in children to examine numeracy and risk information is extremely limited. One study found that children from as young as seven years of age understand probability information but, like adults, the format used to communicate probabilistic information can significantly affect children's accuracy making judgments about the likelihood of an event (Ulph et. al. 2009). Schlottmann argues that children as young as five or six years of age can understand probabilistic information (Schlottmann 2001).

Summary: Using Words of Likelihood vs. Numbers

Even though there is not a “gold standard” of the best way for providers to convey risk information (Bogardus 1999), an emerging body of evidence is starting to show that conveying risk information numerically may be superior to qualitative terms. This may be because different people perceive words differently and people may tend to extremely over-estimate their chances of a risk occurring when qualitative forms of risk estimation are used (Thurmann 2006, Knapp et. al. 2009, Knapp et. al. 2004, Berry et. al. 2002, Berry et. al. 2003).

This research coded for both ways in which providers may choose to present risk information to patients and their caregivers: qualitatively or numerically.

Risk Communication Frameworks to Be Used in this Dissertation

This dissertation was guided by Bogardus’ risk communication framework (Bogardus 1999) and Makoul and Clayman’s model of shared decision-making (2006). This dissertation coded for a discussion of all of Bogardus’ dimensions (2006) for both risks and side effects as well as coding for a discussion of benefits of asthma control medications. In addition to coding whether or not a specific dimension was addressed, this dissertation also coded each statement of risk, side effect, and benefit verbatim that is discussed in the audiotaped medical visit. Finally, this project also coded for whether providers discussed the likelihood of a risk occurring, and if so, did they discuss it in qualitative, numerical, or in both qualitative and numerical terms.

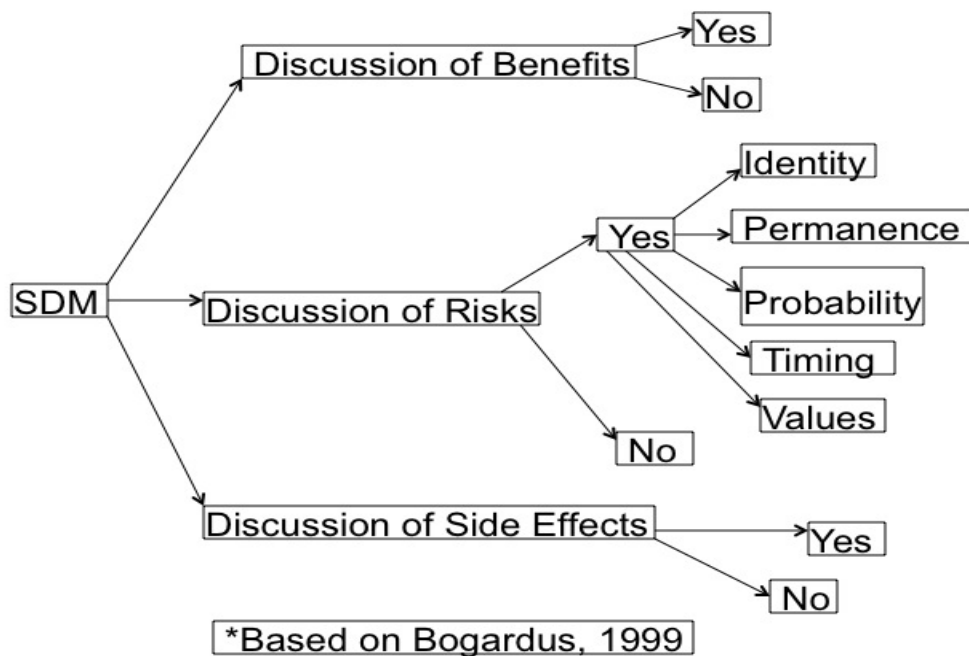
Makoul and Clayman's (2006) model of shared decision-making was also used in guiding this dissertation. This model states that providers should discuss not only the risks of the medication but that providers should also discuss the benefits of the medication. This dissertation coded whether a discussion of the benefits of an asthma control medication occurred during the audio taped medical visit.

Figure 1 shows the schematic of how both Makoul and Clayman's (2006) model of shared decision making and Bogardus' framework of risk communication (1999) provided the framework that was used in coding for risks, side effects, and benefits for this study. The figure shows communication aspects that were coded from transcripts of audio taped medical visits in general pediatric practices in North Carolina, in addition to coding all of the statements and questions regarding risks, side effects, and benefits verbatim from the transcripts. Each transcript was coded for: (1) the presence of a discussion of control medication benefit; (2) the presence of a discussion of control medication risk; (3) the presence of a discussion of control medication side effect; (4) the presence of a discussion of the identity of the risk of the control medication; (5) the presence of a discussion of the permanence of the risk; (6) the presence of a discussion of the probability of a risk; (7) the probability of timing of the risk; and (8) the presence of a discussion of the patient's and caregiver's values regarding the risk.

For the purposes of this dissertation, risks were defined as potential adverse reactions that could occur as a result of using a medication, but have not yet been experienced by a patient using that medication. An example of a risk as defined in this dissertation would

be the risk of oral thrush from ICS medications, as long as the patient has not experienced oral thrush in the past. Side effects were defined as adverse reactions that the patient was experiencing on the day of the visit or had previously experienced prior to the audio taped visit. An example of a side effect as defined in this dissertation would be oral thrush being experienced by the patient at the visit or sometime prior to the visit, since the patient's susceptibility to experiencing the side effect is known. Benefits were defined as positive outcomes, both potential and presently being experienced, that may or will occur as a result of using the medication. An example of a benefit of an ICS medication is the decreased need for short-acting beta-agonist medication use as a result of using the ICS medication.

Figure 1: Framework Used in Coding Communication

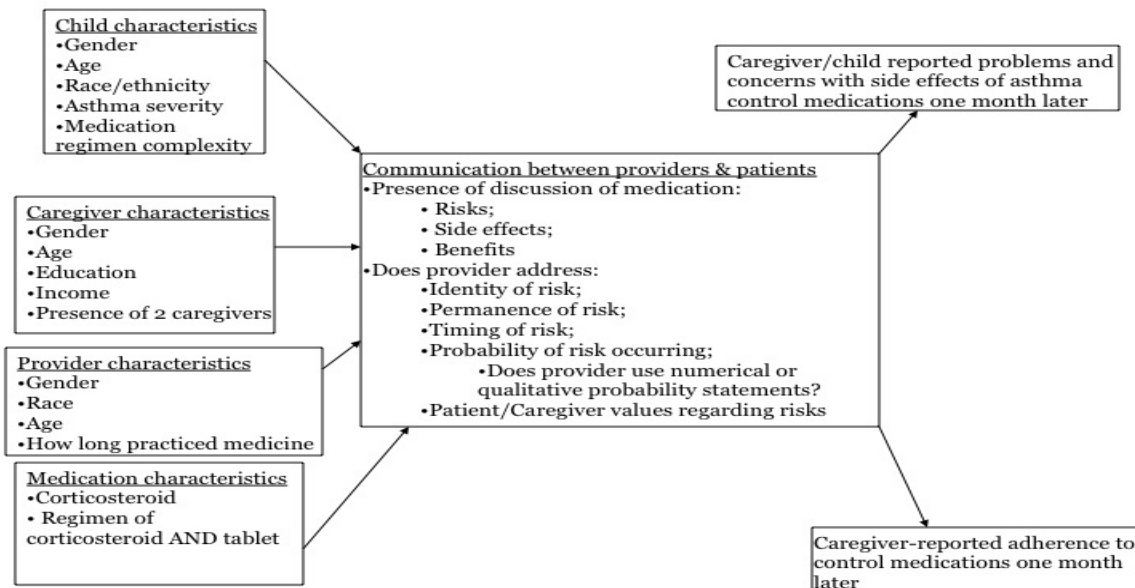


The framework for the conceptual model that shows the relationships between characteristics of the child, caregiver, provider, and medication influence discussion of the risks, side effects, and benefits of asthma control medications and medication adherence and concerns about side effects of asthma medications will be presented in the next section.

Conceptual Model Used in this Dissertation

Figure 2 presents the conceptual model for the study that links side effect, risk, and benefit communication aspects described above to caregiver-reported medication adherence and caregiver and child-reported problems and concerns with side effects one month following the medical encounter. The model suggests that characteristics of the child, caregiver provider, and medication are related to communication between pediatricians, caregivers, and children about the risks, benefits, and side effects of a control medication. The model also suggests that communication about the risks, side effects, and benefits of asthma control medications are related to caregivers and children's concerns about side effects of their control medication and medication adherence one month later.

Figure 2: Conceptual Model Linking Characteristics to Communication and Outcomes



Patient and Caregiver Characteristics

Medical communication research has shown that characteristics of the child and caregiver both play an important role in more parent and child involvement in a medical encounter. Cox et. al. found that passive involvement of parents in a medical encounter was less likely when both parents were present, compared to when mothers who were present (Cox et. al. 2007). Other variables that may affect communication during the medical visit as well as medication adherence are: (1) age of the child; (2) age of the parent, (3) race, (4) income, (5) how long the child has lived with asthma, and (6) asthma severity [Rau 2005]. Additionally, caregivers who are less educated and have lower incomes may also have low numeracy, which could explain why these people may want to know the potential for all adverse effects since they may be uncomfortable dealing with numbers (Zeigler et. al. 2001).

Physician Characteristics

The pediatric medical communication literature suggests that communication between providers, caregivers, and children are a function of characteristics of not only children and their caregivers, but also of providers. Research has shown that children and parents speak longer and are more active in visits with female providers (Bernzweig et. al. 1997). Also, passive involvement of parents was less likely with physicians who have been in practice longer and with longer medical visits (Cox et. al. 2007). Further, studies have consistently shown that different communication styles are predictors of improved health outcomes, such as reassurance, patient – centered questioning techniques, as well as time spent in information and education (Drotar et. al. 2009). Higher treatment adherence has been found among children whose physicians who were viewed more supportive and more interested in the child (Kyngas and Rissanen 2001).

Medication Characteristics

Research has shown that a medication's delivery device may affect treatment adherence among patients with asthma. For example, past research supports the notion that children may adhere better with oral medications (i.e. Singulair) than with metered-dose inhalers (Carter and Ananthakrishnan 2003 and Sherman 2001). Additionally, the complexity of the medication regimen may also affect adherence (Rau 2005). The author of this dissertation hypothesized that medication characteristics, such as mode of administration and medications that contain inhaled steroids may impact discussions of risks, side effects, and benefits of these medications. These discussions could potentially impact medication adherence as well as concerns about side effects of control medications.

Communication between physicians, caregivers, and children

For this study, discussion of risks, benefits, and side effects were variables of interest in assessing the impact of parent, child, physician, and medication characteristics on provider-caregiver-child communication. One study found that more time allotted during the medical visit for risk communication significantly increased the patient's intention to adhere to chosen treatment (Edwards et. al. 2004). Further, questions and statements by children, caregivers, and physicians about risks, benefits, and side – effects are all considered important since improved outcomes have been found to be associated with less passive involvement from children and caregivers (Cox et. al. 2007). Finally, the manner in which providers communicate about the probability of risk is an area of interest because the risk communication literature suggests that how the risk is communicated can impact patient understanding. Furthermore, there is no consensus about how to communicate inherent medical risks (Bogardus 1999). This research used qualitative and numerical statements of risk as a means of assessing risk communication.

Provider-patient communication about medication side effects, risks, and benefits and the potential outcomes that may be associated with this communication make this dissertation practical and important. One of the FDA's research priorities is to investigate how to communicate the risks of medications to the public (US FDA, 2007). This dissertation will increase knowledge about how general medical providers who treat pediatric patients may be discussing asthma control medication-related risks to children and their caregivers as well as present information on the extent to which providers are

discussing risks. The specific aims that this research will address are provided below along with the hypotheses for each aim and the methods used to accomplish each aim.

Specific Aims

1. To examine the association between provider, caregiver, and child characteristics and communication about risks, side effects, and benefits of asthma control medications during audiotaped pediatric visits.

H1: Discussions of asthma control medication side effects will be more likely to be discussed when more than one caregiver is present during the audiotaped medical visit.

H2: Discussions of asthma control medication risks will be more likely to occur when caregivers have lower incomes.

H3: Discussions of asthma control medication risks will be more likely to occur when there is more than one caregiver present during the audiotaped medical visit.

H4: Discussions of asthma control medication risks will be more likely to occur when caregivers are less educated.

H5: Discussions of asthma control medication benefits will be more likely to be discussed when the child has moderate/severe persistent asthma.

2. To analyze predictors of caregiver-reported adherence to the child's asthma control medications one month after the audiotaped medical visit.

H6: Caregivers are more likely to report their child as adherent to their asthma control medications if risks were discussed in the medical visit.

H7: Caregivers are more likely to report their child as adherent to their asthma control medications when the control medication was only montelukast.

H8: Caregivers are more likely to report their child as adherent to their asthma control medications when the child is not taking an inhaled corticosteroid AND a tablet as asthma control medications.

3. To examine the association between risk, side effect, and benefit communication and caregiver- and child-reported problems and concerns about asthma medication side effects one month after the audiotaped medical visit.

H9: Caregivers are less likely to report problems and concerns about side effects with their child's asthma medications if risks were discussed during the medical visit.

H10: Caregivers are less likely to report problems and concerns about side effects with their child's asthma medications if the asthma control medication does not contain an inhaled corticosteroid.

H11: Children are less likely to report problems and concerns about side effects with their asthma control medications if side effects were discussed during the medical visit.

H12: Children are more likely to report problems and concerns about side effects with their asthma control medications if benefits were discussed during the medical visit.

4. To qualitatively describe all control medication risks, side effects, and benefits that are discussed during the audiotaped asthma visits.

Summary and rationale

Asthma is one of the most common chronic diseases in childhood and the research investigating provider–caregiver–patient communication is limited. This dissertation is the first study to examine the actual content of the discussions about asthma control medication-related side effects, risks, and benefits. This dissertation also contributes to the literature by examining factors that are associated with communication of risks, side effects, and benefits of asthma control medications. Finally, this dissertation contributes to the literature by examining if discussions about side effects, risks, and benefits are associated with caregiver-reported medication asthma control medication adherence and child- and caregiver-reported problems/concerns about side effects of control medications.

The findings from this study can be used to develop communication strategies directed toward providers, caregivers, and children with persistent asthma so that asthma outcomes can be improved. The field of risk communication about medications is currently in its infancy, therefore this research will contribute to a better understanding of risk communication about control medications during pediatric asthma visits.

CHAPTER TWO: METHODS FOR QUANTITATIVE ANALYSIS (AIMS 1-3)

Overview

This study is a cross-sectional secondary analysis of data collected from a previous NHLBI funded study examining physician-caregiver-child communication about asthma communication in primary care visits. The data were collected from June 2006 through October 2009. The study sample includes 296 pediatric patients with persistent asthma and 35 medical providers from North Carolina. Study data includes de-identified clinic visit audiotapes, child interviews, and caregiver surveys. The University of North Carolina-Chapel Hill Institutional Review Board approved this study.

Medical providers, children, and caregivers provided consent/assent for the parent study. The aims of this research were developed after patient enrollment was completed under the protocol of the parent grant. Providers, children, and caregivers were therefore blinded to the specific aims outlined in this research.

Study Setting

Providers, children, and their primary caregivers were recruited from five primary care pediatric clinics, all of which are located in North Carolina. Thirty-five providers from the five offices agreed to participate in the study. Providers were eligible to participate if they regularly treated pediatric asthma patients. Written consent was obtained from each

participating provider. All of the clinics accepted Medicaid in addition to private insurance; this is advantageous because offices that accept Medicaid are more likely to serve a racially and economically diverse patient population (Dubay, 2002).

Patient Enrollment and Eligibility

Patients were eligible for the study if they were: (1) between the ages of 8 and 16, (2) had a prior diagnosis of asthma, (3) read and spoke English, and (4) classified by a research assistant as having mild or moderate/severe persistent asthma based on medications and symptom-frequency over the past year. Mild persistent asthma was defined as: (1) the child is on one control medication (e.g. montelukast) and/or (2) the child has experienced asthma symptoms (e.g. coughing or wheezing) more than two times per week, but not every day for the past year. Moderate/severe persistent asthma was defined as: (1) the child is on two control medications (e.g. fluticasone/salmeterol combination) and/or (2) the child has experienced at least one asthma symptom every day for the past year (NAEPP, 2002). Each child and caregiver dyad completed an eligibility screener before enrollment into the parent study. Research assistants obtained written assent/consent from each child and his/her caregiver.

Data Collection and Variables

Data Collection Procedures

Clinic staff identified children with asthma who had an upcoming office visit; the clinic staff called caregivers the day prior to their visit to remind them of the visit and to briefly describe the parent study. On the day of the visit, clinic staff referred interested patients and caregivers to research staff, who described the study in more detail. If the patient and

caregiver were willing to participate in the study and met all eligibility criteria, then the research assistant enrolled them in the waiting room prior to the patient being called to see the provider. Before the provider entered the exam room, a research assistant set up a digital audio-recorder and microphone, started recording, and exited the room. When the physician was finished with the visit, the research assistant then re-entered the room and stopped the recorder. The research assistant then moved both the child and caregiver to another room within the clinic. The caregiver then completed a questionnaire while the research assistant interviewed the child. Approximately one month after the initial clinic visit, the research assistant went to the child's residence and interviewed the child again while the parent completed a questionnaire. As part of both the initial clinic visit and home visit, the research assistant recorded self-reported medication adherence for control medications from both the child and caregiver. Children and their caregivers were given \$15 each at both the initial clinic and home visits.

Data

The majority of the data for this research came from three primary sources: (1) transcripts from the audio taped medical visits; (2) interviews administered to the child by a research assistant at the conclusion of the medical visit and one month after the audio taped medical visit; and (3) questionnaires completed by the caregiver immediately after the medical visit and one month after the medical visit. Additional data came from the eligibility screeners and a survey completed by the providers when they agreed to participate in the parent study.

All communication variables were coded from the transcriptions of the audiotapes. The Primary Coding Instrument (PCI) was developed under the protocol of the parent study. The Supplemental Coding Instrument (SCI) was developed for this research.

Transcript Generation

All audiotapes were transcribed under the protocol of the parent grant. Transcribing occurred under the supervision of the principal investigator of the parent grant.

Transcriptions of audiotapes make the coding of the audiotapes more reliable (Waitzkin 1990 and Mishler 1984). The principal investigator of the parent grant had previously used the transcribing rules that were used in the parent study. The transcribing rules were adapted from transcribing rules used by previous researchers in physician-patient communication (Waitzkin 1990 and Mishler 1984). All identifiers were removed when the audiotapes were transcribed. The transcriptionists were blinded to the study hypotheses.

Coding: Primary Coding Instrument (PCI)

The Primary Coding Instrument (PCI) was developed as part of the parent grant. The principal investigator trained research assistants how to code the transcripts using the PCI. Coders were trained using 12 transcripts from a pilot study. During training, the minimum accepted level for inter-rater reliability was 0.80. Practice and training continued until this minimum level of reliability was achieved. After coders achieved this minimal level of reliability, they started coding the transcripts from the parent study. All coders blindly coded 20 of the same transcripts to ensure the minimum level of

reliability. To assure that reliability levels were maintained, the principal investigator conducted spot checks of coder performance throughout the coding process. If there was a problem in the coder's performance, the coder was immediately stopped from coding more transcripts and re-trained until the minimum reliability level of 0.80 was achieved. Like the transcriptionists, the coders were blinded to the parent study's hypotheses. This dissertation did not use any communication variables from the PCI.

Coding: Supplemental Coding Instrument (SCI)

The transcripts were also coded using a supplemental coding instrument that was developed specifically for this research. The rules that were followed by the coders can be found in Appendix A and the actual coding tool can be found in Appendix B. The author of this dissertation developed a draft of the supplemental instrument, which was refined and tested during the initial part of this study. Another coder was trained to code the transcripts using ten transcripts from a pilot study. Using the coding tool for transcribed medical visits, coders recorded the following: (1) the verbatim questions that providers, caregivers, and children asked about asthma control medication side effects, risks, and benefits; (2) the number of questions that each participant asked about asthma control medication side effects, risks, and benefits; (3) the verbatim statements that providers, caregivers, and children made about asthma control medications side effects, risks, and benefits; (3) the number of statements that each participant made about asthma control medication side effects, risks, and benefits; (4) the initiator of each conversation about asthma control medication side effects, risks, and benefits, (5) the end-of-visit plan

for each medication discussed during the medical visit; and (6) whether there was more than one caregiver present during the medical visit.

The principal investigator of this dissertation trained another coder to ensure that the results of this dissertation was more reliable and reproducible. After initial training, both coders coded 20 of the same transcripts throughout the coding period to assess inter-coder reliability using Cohen's kappa coefficient. The kappa coefficient for inter-coder reliability was 1.00 for discussion of side effect, 1.00 for discussion of risk, and 0.80 for discussion of benefit.

The coders met once weekly to discuss the coding of transcripts as well as to define the categories of questions and statements about side effects, risks, and benefits. The name of each category is meant to reflect the general concept assessed by each question and statement

Measurement

Table 3 describes all of the outcome measures that were used in this research. All variables are defined below. The outcome measures that were used in this study came from three sources: (1) transcripts of the audio tapes of the medical visits; (2) interviews completed by children one month after the audiotaped medical visit; and (3) questionnaires completed by one month after the audiotaped medical visit;

Table 3: Outcome Variables, Source, and Range

Variable Outcomes	Source	Range
Adherence score to asthma control medications one month after visit	Caregiver Questionnaire	Continuous; Range = 0-100.0
Adherent to asthma control medications one month after visit	Caregiver Questionnaire	Adherence score of at least 80% indicates child was adherent (1); adherence score of less than 80% indicates child was not adherent (0)
Caregiver Side Effects Concern about asthma control medications one month after visit	Caregiver Questionnaire	1=yes; 0=no
Child Side Effects Concern about asthma control medications one month after visit	Child Interview	1=yes; 0=no

Outcome Variables (From Caregiver Questionnaire and Child Interview at Home Visit)

Adherence Score: This continuous variable indicates the child's adherence to asthma control medications as a percentage with values ranging from 0% to 100%. Adherence from caregiver self-report data was measured using the following formula: adherence = (number of doses used during the past week divided by the number of prescribed doses) multiplied by 100. Children who were on more than one asthma control medication had an average adherence score calculated.

Adherent: This dichotomous variable indicates whether the caregiver reported whether the child was adherent to their asthma control medications. "Yes" (1) indicated the child had an adherence score (or average adherence score) of at least 80%. "No" (0)

indicated the child had an adherence score (or average adherence score) that was less than 80%. Eighty percent has been used in many prior studies as reflective of adequate adherence (Karve et. al. 2009).

Caregiver Side Effects Concern: This variable indicates the level of problems/concerns about side effects that caregivers reported at the home visit. Options for caregivers in the parent study were: 0=none, 1=a little, and 2=a lot. This variable was taken from the caregiver's home visit questionnaire. The answers to this question in the parent study were skewed to the left because of numerous values where the caregiver reported no concern/problem about side effects; consequently, this variable was transformed into a dichotomous variable. "Yes" (1) indicates that the child's caregiver reported a little or a lot of concern about their child's asthma medication and "No" (0) indicates that the caregiver chose "None" on the survey about concern/problem of side effects from their child's asthma medication.

Child Side Effects Concern: This variable indicates the level of problems/concerns about side effects that children reported at the home visit. Options for children were 0=none, 1=a little, and 2=a lot in the parent study. This variable was taken from the child's home visit interview. The answers to this question in the parent study were skewed to the left because of numerous values where the child reported no problem/concern about side effects; consequently, this variable was transformed into a dichotomous variable. "Yes" (1) indicates the child reported a little or a lot of concern

with side effects from their asthma control medication and “No” (0) indicates that the child did reported no concern about side effects of their asthma medication.

Communication, Medical Visit, and Medication Variables (Based on Coding of Transcripts of Audiotapes)

This section describes the variables that were measured as aspects of both the communication that occurred during the medical visit and aspects of the actual medical visit. **Table 4** presents the communication and medical visit variables that were used in this dissertation, including the name of the variable as well as the range. All of the variables presented in **Table 4** came from the secondary coding tool.

Table 4: Communication, Medical Visit, and Medication Variables

Communication & Medical Visit	Range
Benefits discussed of asthma control medications	1=yes; 0=no
Side effects of control medications discussed	1=yes; 0=no
Risks of control medications discussed	1=yes; 0=no
Number of caregiver statements about benefits of asthma control medications	Discrete (0-7)
Number of caregiver questions about benefits of asthma control medications	Discrete (0-1)
Number of provider statements about benefits of asthma control medications	Discrete (0-9)
Number of provider questions about benefits of asthma control medications	Discrete (0-8)
Caregiver States Side Effects of asthma control medications	1=yes; 0=no
Child State Side Effects of asthma control medications	1=yes; 0=no
Number of child statements about side effects of asthma control medications	Discrete (0-1)

Communication & Medical Visit	Range
Number of child questions about side effects of asthma control medications	Discrete (0)
Number of caregiver statements about side effects of asthma control medications	Discrete (0-2)
Number of caregiver questions about side effects of asthma control medications	Discrete (0-1)
Number of provider statements about side effects of asthma control medications	Discrete (0-4)
Number of provider questions about side effects of asthma control medications	Discrete (0-3)
Risk identified	1=yes; 0=no
Risk permanence	1=yes; 0=no
Risk timing	1=yes; 0=no
Probability discussed	1=yes; 0=no
Numerical statements about probability of risk from asthma control medications	1=yes; 0=no
Qualitative statements about probability of risk from asthma control medications	1=yes; 0=no
Child values discussed about risks of asthma control medications	1=yes; 0=no
Caregiver values discussed about risks of asthma control medications	1=yes; 0=no
Number of child statements about risks with medications	Discrete (0)
Number of child questions about risks with medications	Discrete (0-1)
Number of caregiver statements about risks with medications	Discrete (0-2)
Number of caregiver questions about risks with current medications	Discrete (0-2)
Number of provider statements about risks with medications	Discrete (0-6)
Number of provider questions about risks with medications	Discrete (0-2)
Medication Characteristics	
Corticosteroid	1=yes; 0=no
Number of Asthma Control Medications Discussed	Discrete (0-4)
Number of Asthma Control Medications Started	Discrete (0-2)
Number of Asthma Control Medications Continued	Discrete (0-3)

Medication Characteristics	Range
Number of Asthma Control Medications Discontinued	Discrete (0-2)
Child Taking Singulair and an Inhaled Corticosteroid	1=yes; 0=no
Child Taking Singulair Only	1=yes; 0=no

Benefits of asthma control medications discussed: This dichotomous variable indicates whether there was a discussion of benefits of an asthma control medication. “Yes” (1) indicated that there was a discussion of benefits of an asthma control medication and “No” (0) indicated there was not a discussion of the benefits of an asthma control medication. Examples of benefits of an asthma control medication could be “prevents wheezing” and/or “less frequent use of a rescue medication.”

Side Effects Discussed: This dichotomous variable indicates whether there was a discussion about the side effects of the current asthma control medication(s) being taken. If the child was not on an asthma control medication on the day of the visit, then this variable did not apply. “Yes” (1) indicates that there was a discussion of side effects and “No” (0) indicates that there was not a discussion of side effects. A side effect was defined as an adverse reaction that the patient/child was experiencing at the time of the visit or has been experienced in the past from a medication that the child was taking or had taken in the past. An example of a side effect is “bad taste from a metered dose inhaler.”

Risks Discussed: This dichotomous variable indicates whether there was a discussion of the risks of an asthma control medication. “Yes” (1) indicates that there was a

discussion of risks and “No” (0) indicates there was not a discussion of risks. A risk was defined as an adverse reaction that the patient/child had not experienced yet while taking an asthma control medication. A risk was also defined as an adverse reaction that the child may experience before starting a new asthma control medication. An example of a risk would be the potential for a corticosteroid metered-dose inhaler to potentially cause oral candidiasis (oral thrush), but the child had not experienced that adverse reaction previously.

Length of visit: This discrete variable indicates the length in seconds of the audiotaped visit.

Number of statements of benefits of asthma control medications: There were three separate discrete variables that measured the number of statements about benefits that were made during the audiotaped medical visits. There was a variable that measured the number of statements about benefits made by providers, another variable that measured the number of statements about benefits made by caregivers, and the last variable that measured the number of statements about benefits made by children.

Number of questions about benefits of asthma control medications: There were three separate discrete variables that measured the number of questions about benefits that were made during the audiotaped medical visits. One variable measured the number of questions about benefits that providers asked, another variable that measured the

number of questions about benefits that caregivers asked, and the last variable that measured the number of questions about benefits that children asked.

Number of statements of side effects of asthma control medications: There were three separate discrete variables that measured the number of statements about side effects that were made during the audiotaped medical visits. One variable measured the number of statements about side effects that providers made, another variable that measured the number of statements about side effects that caregivers made, and the last variable measured the number of statements about side effects that children made.

Number of questions about side effects of asthma control medications: There were three separate discrete variables that measured the number of questions about side effects that were made during the audiotaped medical visits. One variable measured the number of questions about side effects asked by providers, another variable that measured the number of questions about side effects asked by caregivers, and the last variable that measured the number of questions about side effects asked by children.

Risk Identified: This dichotomous variable indicates whether the provider stated any risks of an asthma control medication. “Yes” (1) indicates that the provider did identify a risk associated with an asthma control medication and “No” (0) indicates the provider did not identify a risk. An example of a provider identifying a risk would be: “There are some risks. What risks? There are some studies that say using long-acting beta agonists increase the risk of asthma-related death.”

Permanence of Risk Discussed: This dichotomous variable indicates whether the provider made any statements about how long each stated risk would affect the child. “Yes” (1) indicates that there was a discussion of the permanence of a risk and “No” (0) indicates there was not a discussion. An example of this type of communication would be the provider discussing: is the risk temporary or permanent (reduced height from ICSs may be temporary).

Timing of Risk Discussed: This dichotomous variable indicates whether there was a discussion of when the risk is likely to occur. “Yes” (1) indicates that timing of a risk was discussed and “No” (0) indicates that it was not discussed. Examples that would lead to a coding of “Yes” (1) would be the provider addressing: (a) when the risk is likely to occur (i.e. how long it will take for child to experience oral candidiasis), and (b) discussing and weighing of risks that may happen now versus later on in the treatment process (reduced height from asthma severity versus potential for reduced height from using ICSs).

Probability Discussed: This dichotomous variable indicates if the provider communicated any probability of the child experiencing a risk and/or side effect. “Yes” (1) indicates the provider did use at least one type of probability statement and “No” (0) indicates the provider did not state any type of probability. An example of a probability statement would be: “There is a rare chance of oral thrush from an inhaled corticosteroid.”

Numerical statements: This dichotomous variable indicates if the provider used any numerical statements of risk during the audiotaped medical visit. “Yes” (1) indicates the provider did use a numerical statement of risk and “No” (0) indicates the provider did not. Examples of numerical statements of risk would be a provider stating the child has a 2% risk of developing oral thrush from using a fluticasone (Flovent) metered-dose inhaler and/or a provider telling a child and caregiver that there is a 1.8% risk of drowsiness when taking montelukast (Singulair).

Qualitative statements: This dichotomous variable indicates whether the provider used any qualitative statements, such as words to communicate risk, during the audiotaped medical visit. “Yes” (1) indicates the provider used a qualitative statement of risk and “No” (0) indicates the provider did not. Any statement of risk that includes words instead of numbers to indicate the probability of a risk occurring was coded as “Yes” (1). Examples of qualitative statements of risk would be the use of these words to describe the probability of a risk occurring: (a) rare, (b) often, (c) not common, (d) unknown risk, (e) high risk, (f) low risk, etc. All qualitative statements were coded verbatim from the transcripts.

Child values addressed: This dichotomous variable indicates the presence of a discussion about the child’s values regarding the risks of their asthma control medication. “Yes” (1) indicates that there was a discussion of the child’s values regarding the risk of the asthma control medication and “No” (0) indicates there was not a discussion. An

example of this type of communication would be the provider asking the child if he/she felt like it was beneficial to take an asthma control medication based on the risks discussed.

Caregiver values addressed: This dichotomous variable indicates the presence of a discussion about the caregiver's values regarding the risks of the asthma control medication. "Yes" (1) indicates that there was a discussion of the caregiver's values regarding the risk and "No" (0) indicates that there was not a discussion. An example of this type of communication would be the provider asking the caregiver if he/she felt comfortable with the child taking a certain asthma control medication based on the risks associated with the medication.

Number of statements of risks: There were three separate discrete variables that measured the number of statements about asthma control medication risks that were made during the audiotaped medical visits. One variable measured the number of statements about risks made by providers, another variable that measured the number of statements about risks made by caregivers, and the last variable that measured the number of statements about risks made by children.

Number of questions about risks: There were three separate discrete variables that measured the number of questions about risks that were asked during the audiotaped medical visits. One variable measured the number of questions about risks asked by providers, another variable that measured the number of questions about risks asked by

caregivers, and the last variable that measured the number of questions about risks asked by children.

Qualitative Coding of Risks, Side Effects, and Benefits: This dissertation also coded all statements and questions of risks, side effects, and benefits made by providers, caregivers, and children. All statements and questions of risks, side effects, and benefits were coded from the transcripts. Statements and questions posed by providers, caregivers, and children were coded. A draft of the SCI is included in Appendix A.

Inhaled Corticosteroid: This dichotomous variable indicated whether any of the child's asthma control medications contained an inhaled corticosteroid. "Yes" (1) indicated that at least one of the child's asthma control medications contained an inhaled corticosteroid and "No" (0) indicated that none of the child's asthma control medications contained an inhaled corticosteroid, meaning that the child was only on Singulair or was not taking any control medications.

End of Visit Plan: These variables indicated the end-of-visit plan for each asthma control medication discussed during the medical visit. These variables were a series of separate dichotomous variables for each asthma control medication discussed. The options for these variables were: (1) start, (2) continue, (3) discontinue, and (4) not start. If the provider started a new asthma control medication or changed the dosage on an asthma control medication, then the Start variable was coded "Yes" (1) and all other **End of Visit** variables would be coded "No" (0). If the provider continued an asthma control

medication, then the Continue variable was coded “Yes” (1). If the provider discontinued an asthma control medication, then the Discontinue variable was coded “Yes” (1). If the provider discussed an asthma control medication but did not start the medication, then the Not Start variable was coded “Yes” (1).

Child Taking Montelukast and an Inhaled Corticosteroid as Asthma Control

Medications: This dichotomous variable measured whether children were taking a medication with an inhaled corticosteroid AND a tablet (i.e. Singulair) as their asthma control medications.

Number of Asthma Control Medications Discussed: This discrete variable measured how many asthma control medications were discussed during the medical visit.

Number of Asthma Control Medications Started: This discrete variable measured how many asthma control medications were started during the medical visit.

Number of Asthma Control Medications Continued: This discrete variable measured how many asthma control medications were continued during the medical visit.

Number of Asthma Control Medications Discontinued: This discrete variable measured how many asthma control medications were discontinued during the medical visit.

Child Only Taking Montelukast: This dichotomous variable measured whether the child was only taking Singulair as the asthma control medication. This variable was conceptualized as identifying children who only took tablets as their asthma control medication versus children who used other devices or a combination of other devices along with tablets. “Yes” (1) indicated the child was only taking Singulair at the time of the home visit and “No” (0) indicated the child did not take Singulair at all, or took Singulair as part of a combination of oral and inhaled pharmacotherapy for asthma.

Child, Caregiver, and Provider Variables

This section describes the variables that were measured for the child, caregiver, provider, and asthma control medications. Unless otherwise noted in **Table 5**, all of these variables were obtained through the child interview or caregiver and provider questionnaire. **Table 5** presents these variables, including the variable name, source, type, and range.

Table 5: Child, Caregiver, Provider, and Medication Variables

Child Characteristics	Source	Type (Range)
Gender	Child Interview	1=male; 0=female
Age	Child Interview	Continuous (8-16)
Race/ethnicity	Child Interview	1=white; 0=non-white
How long child has lived with asthma	Child Interview	Continuous
Asthma severity	Child Interview	1=moderate/severe persistent; 0=mild persistent
Child on Medicaid	Caregiver Questionnaire	1=yes; 0=no
Number of Prior Visits with Study Provider	Caregiver Questionnaire	Discrete (0-70)

Caregiver characteristics	Source	Type (Range)
Gender	Caregiver Questionnaire	1=male; 0=female
Age	Caregiver Questionnaire	Continuous (26-80)
Education	Caregiver Questionnaire	Continuous (2-20)
Income	Caregiver Questionnaire	1=Less than \$10,000 2=Between \$10,000 and \$19,999 3=\$20,000 through \$29,999 4=\$30,000 through \$49,999 5=\$50,000 through \$69,999 6=\$70,000 or more
Presence of 2 caregivers	Coding Tool	1=yes; 0=no
Provider characteristics	Source	Type (Range)
Gender	Provider Questionnaire	1=male; 0=female
Age	Provider Questionnaire	Continuous (29-69)
How long has practiced medicine	Provider Questionnaire	Continuous (1-43)
Race	Provider Questionnaire	1=white; 0=non-white

Child Variables (Obtained from the Child Interview at Initial Visit and Home Visit)

Gender: This dichotomous variable measures whether the child was either male or female, reported by the child.

Age: This continuous variable measures the age of the child in years, reported by the child.

Race/ethnicity: This variable was originally reported by children as: White, African – American, Native American, Asian, and Other. Race was recoded as a dichotomous variable for analyses, measuring whether the patient was White or Non-White. “Yes” (1) indicates the child was white and “No” (0) indicates the child was not White.

Number of Prior Visits with Study Provider: This discrete variable indicated the number of times the child had previously seen the provider that was seen as part of the medical visit. This variable was caregiver-reported.

Asthma severity: This dichotomous variable indicates the severity of the child’s asthma. Mild persistent asthma was coded (0) and moderate/severe persistent asthma was coded (1). This variable is based on the parent study’s eligibility screener which classified children’s severity based on two methods: asthma symptoms and medication use. Any child receiving a single asthma control medication was classified as mild persistent. Any child receiving more than one asthma control medication was classified as moderate/severe persistent. Any subject that reported symptoms occurring two or more times a week but not daily or waking up more than two or more times a month, but not nightly, was classified as mild persistent. Any subject that reported symptoms occurring every day or waking up more than five times a month was classified as moderate/severe persistent (NAEPP, 2002).

Child on Medicaid: This dichotomous variable indicates whether the child had Medicaid at the time of the audiotaped medical visit. Insurance type was originally a

categorical variable in the parent study, using the following categories: None, Private, Medicaid, North Carolina Health Choice, and Other. The majority of children were using Medicaid, with smaller amounts of children being covered by private insurance and North Carolina Health Choice (NCHC) so this variable was transformed into a dichotomous variable for the bivariate and multivariate analyses. “Yes” (1) indicates the child had Medicaid and “No” (0) indicates the child did not.

Caregiver Variables

Gender: This dichotomous variable indicates whether the caregiver present during the audiotaped visit was male or female. If more than one caregiver was present, this variable indicates the gender of the caregiver who filled out the questionnaire.

Age: This continuous variable indicates the age in years of the caregiver present during the audiotaped visit. If more than one caregiver was present, this variable indicates the age in years of the caregiver who filled out the questionnaire.

Education: This discrete variable indicates the number of years the caregiver has spent in formal education, reported by the caregiver.

Income: This variable indicates the amount of income in US dollars the household receives. The categories are: (a) less than \$10,000, (b) \$10,000 - \$19,999, (c) \$20,000 - \$29,999, (d) \$30,000 - \$49,999, (e) \$50,000 - \$69,999, or (f) \$70,000 or more. For the bivariate and multivariate analyses, total household income was dichotomized, \$19,999

or less versus \$20,000 or more. This was chosen because \$20,000 or less was classified as the federal poverty level in 2006, when data collection commenced for the parent study (US Department of Health and Human Services, 2006). The variable was coded as: (1) for families that made at least \$20,000 and (0) for families that made less than \$20,000.

Presence of two caregivers: This dichotomous variable indicates whether there was more than one caregiver present during the audio – taped visit and were taken from the transcripts of the visit.

Provider Variables (Obtained from the Provider Questionnaire)

Gender: This dichotomous variable indicates whether the provider is male or female. This measure was self-reported by the provider.

Race: This variable indicates the provider's race. The original categories for this variable in the parent study were: White, African American, Native American/American Indian, or Other (includes categories of Hispanic, Asian American, other). This variable was transformed into a dichotomous variable for the analyses where providers who were White were coded (1) and providers who were Non-White were coded (0) because of low frequencies of non-white races.

Age: This continuous variable measured how old the provider was in years at the time of provider enrollment.

How long practiced medicine: This discrete variable indicates how many years it had been since the provider graduated from medical school. The year of graduation was subtracted from the year that the provider completed the provider survey.

Creation of Composite Variables

Racial Concordance: A new variable, **Racial Concordance**, was created to indicate medical visits in which the race of the child matched the race of the provider. This variable was created because of the importance of race concordance on medical visit communication and medication outcomes (Johnson et. al. 2004). Specifically, provider-patient communication may be improved when the patient's race matches the provider's race (Johnson et. al. 2004). Racial concordance between providers and patients is also significantly related to improved patient outcomes (LaVeist and Nuru-Jeter 2002).

The next section is a discussion of the calculation of the sample size that was used in this study to make sure there was adequate power to detect meaningful conclusions.

Sample Size and Statistical Power

This research used an estimate of sample size that was described by Bentler et. al (1976). This heuristic is a general method of determining the number of subjects that are needed for a study. This heuristic suggests that when regression analyses are used a sample size of: $80 + 20 \times \sqrt{\text{number of independent variables}}$. The largest numbers of variables were in the analyses for Aim 2 ($n=21$) and therefore 172 persons were estimated to be able to

detect a significant difference ($80+20*4.6$). Therefore, 295 subjects provided adequate statistical power for the current study.

The next section is a discussion of missing data and the methods employed to remedy the problems caused by missing data.

Missing Data

The data were next examined for the presence of missing data. The patterns of missing data are reviewed next, which determined the method for addressing the problem. **Table 6** below shows the variables that were missing along with the frequency and percent missing.

Table 6: Variables with Missing Data (N=295)

Variable Name	Frequency Missing (%)
Child has Medicaid as Insurance	9 (3.1%)
Caregiver is Married	3 (1.0%)
Asthma Reason for Medical visit	2 (0.7%)
Child is Hispanic	6 (2.0%)
Child is white	6 (2.0%)
Caregiver Gender	1 (0.3%)
Caregiver Age	14 (4.7%)
Caregiver Years of Education	4 (1.4%)
Total household income	7 (2.4%)
Number of prior visits with study provider	36 (12.2%)
Adherent	59 (20.0%)
Caregiver Concern about Side Effects	37 (12.5%)
Child Concern about Side Effects	40 (13.6%)

The missing data can be attributed to at least three causes: (a) improper following of skip patterns, (b) willful incompleteness of the items, and (c) children who were lost to follow-

up or dropped out of the study. One patient did not have any baseline information, which left a baseline sample of 295 children.

There was no way to evaluate whether the data were missing at random, since this would require knowledge of the missing values. However, Faris and colleagues (2002) showed that even when there are violations of the missing at random assumption, that the bias that is introduced to regression coefficients was minimal. Therefore, a conservative approach to analyze the missing data was chosen and the data was assumed to be missing at random (MAR). For this study, multiple imputation methods were utilized to address the missing data in the predictor variables. Multiple imputation models using the Markov Chain Monte Carlo (MCMC) algorithm method with five imputed datasets were created.

Generalized estimating equation (GEE) models for each of the communication outcome variables (**Side Effects Discussed, Risks Discussed, and Benefits Discussed**) were constructed for the multiply-imputed dataset and for the complete case dataset using listwise deletion. There were few differences in the coefficients and no differences in the variables that were of statistical significance when comparing the multiply-imputed dataset and the complete case dataset using listwise deletion. Results from the complete cases are presented in the results. The sample size for the GEE model predicting risk and benefit discussion was 255.

There were also missing variables on three of the outcome variables, adherence, and whether the caregiver and child had any concerns or fears about side effects. In total, 260

children and caregivers had home visits; therefore, 88% of the final sample completed both data points for the study. There is debate around imputing outcome variables, thus the decision was made to use complete case analysis using listwise deletion of missing values on outcome variables. Listwise deletion removes subjects from the analysis if there is a missing value on any of the variables that were included in the model.

The listwise deletion left a sample of 229 caregivers that answered the home visit variable, adherence. The sample size for the adherence outcome variable was 214 after accounting for missing data in the independent variables. The sample size for the caregiver concern at home visit outcome variable was 215 and the sample size for the child concern at home visit outcome variable was 240. Even though these sample sizes did decrease the overall power of this dissertation, the sample sizes were still well above the minimum amount of patients needed to detect significant differences ($n=172$).

Data Analysis

All study data were entered into SPSS 14.0 and converted to SAS 9.2 for analysis. In addition, codes were entered into Excel 2011 from the qualitative analysis.

Descriptive Data Analysis

First, descriptive statistics were calculated for the child, caregiver, provider, medication, and communication variables. Frequencies and percents were used to describe categorical and dichotomous variables. Means and standard deviations were used to describe continuous variables. For all discrete and count variables, the data was plotted

to examine the structure. As an example, the child question asking about risks variable was skewed to the left because of numerous zero values, therefore it was dichotomized.

Bivariate Data Analysis

Bivariate relationships among the independent variables were examined using Pearson correlation coefficients. **Table 18** in CHAPTER FOUR presents the correlations for the independent variables that were used in this dissertation.

After the bivariate relationships among the independent variables were examined, the, bivariate relationships between all of the outcome variables and child, caregiver, provider, medication, visit, and communication characteristics were examined. **Table 19** in CHAPTER FOUR presents the correlations among the independent variables with each outcome variable used in this dissertation. **Table 19** shows Pearson correlation coefficients.

After examining the Pearson correlation coefficients between the independent variables and the outcome variables, chi-square statistics were calculated to test the association between each of the outcome variables and categorical independent variables. Two-tailed t-tests were calculated to test the association between communication outcome variables and discrete variables. All analyses were conducted with an alpha level of 0.05 and performed in SAS 9.2.

Multicollinearity Among Independent Variables

As expected, there was significant multi-collinearity between the caregiver-reported race variable and the child-reported race variable ($r=0.81$, $p<0.0001$). Thus, only child-reported race was used in the bivariate and GEE analyses. There was also significant multi-collinearity between the provider's age and the length of time that the provider had spent in medical practice ($r=0.92$, $p<0.0001$). Therefore, only provider age was used in the bivariate and GEE analyses for all outcome variables.

There was multicollinearity between the number of control medications discussed and the number of control medications that the child was taking or prescribed at the end of the visit ($r=0.74$, $p<0.0001$). This correlation is intuitive because the number of medications that were discussed during the visit would be the exact same or very close to the number of control medications that were continued or prescribed. Another set of variables that breached the $r=0.70$ threshold for multicollinearity were the number of control medications that the child was taking or prescribed at the end of the visit and the number of control medications that were continued during the visit ($r=0.76$). There was also significant multicollinearity between the variable that measured patients who were taking inhaled corticosteroids and the number of medications the patient was taking ($r=0.62$, $p<0.0001$). This relationship did not meet the $r=0.70$ threshold (Slinker and Glantz 1985) but the relationship was approaching the threshold. The decision was made to drop the number of medications the child was taking or prescribed at the end of the visit for all primary analyses except the analysis that focused on medication adherence. For the medication adherence analysis, the number of medications that the child was taking was

used and the variable that measured whether the child was taking an inhaled corticosteroid was dropped.

To remedy this multicollinearity, the decision was made to drop the number of the number of medications the child took or was prescribed to take at the end of the visit and number of control medications that were continued during the visit, in favor of keeping the number of medications discussed during the visit variable for the primary analyses.

Another set of variables that resulted in multicollinearity was the family income variable and the child on Medicaid variable. While these two variables did not reach the $r=0.70$ threshold to indicate that multicollinearity would be a problem in the multivariate analyses there was a strong, direct correlation between the two variables ($\phi=0.59$, $p<0.0001$). This correlation was the third highest correlation among independent variables and was reaching the $r=0.70$ correlation threshold that may have resulted in multicollinearity problems.

The next section discusses the methods that were used for hypothesis testing using generalized estimating equations for each of the outcome variables.

Analysis by Aim

Specific Aim #1: To examine the association between provider, caregiver, and child characteristics and communication about risks, side effects, and benefits of asthma control medications during audiotaped pediatric visits.

H1: Discussion of asthma control medication side effects will be more likely to be discussed when there is more than one caregiver is present during the audio-taped medical visit.

H2: Discussions of asthma control medication risks will be more likely to occur when caregivers are less educated.

H3: Discussion of asthma control medication risks will be more likely to occur when caregivers have lower incomes.

H4: Discussion of asthma control medication risks will be more likely to occur when there is more than one caregiver present during the audio-taped medical visit.

H5: Discussion of asthma control medication benefits will be more likely to occur when the child has moderate/severe persistent asthma.

These hypotheses were tested using generalized estimating equations (GEE). GEE allows for nesting by provider. GEE models were not constructed for the side effects variable because there was not enough variation to run an appropriate specified GEE model. Only 4% of visits included a discussion about side effects of asthma control medication.

The independent variables for the risk discussion GEE model were: child race, child age, child gender, asthma severity, whether the child was taking an inhaled corticosteroid, caregiver age, caregiver gender, caregiver education, family income, provider gender, provider age, provider race, length of visit, adherence was discussed, presence of second caregiver in room, reason for visit, whether the caregiver was married, the number of prior visits with study provider, and the racial concordance variable.

A separate GEE model was then run to examine the impact of the independent variables on the presence of discussions about the benefits of asthma control medications. The independent variables for this GEE model were: child race, child age, child gender, asthma severity, whether the child was taking or prescribed an inhaled corticosteroid, caregiver age, caregiver gender, family income, provider gender, provider age, provider race, length of visit, whether adherence was discussed, presence of second caregiver in room, reason for visit, whether the caregiver was married, the number of prior visits with the study provider, and the racial concordance variable.

Specific Aim #2: To analyze predictors of caregiver-reported adherence to the child's asthma control medications one month after the audiotaped medical visit.

H6: Caregivers are more likely to report their child being adherent to their asthma control medications if risks were discussed in the medical visit.

H7: Caregivers are more likely to report their child being adherent to their asthma control medications when the control medication was only Singulair.

H8: Caregivers are more likely to report their child being adherent to their asthma control medications when the child is taking only one asthma control medication or one combination asthma control medication.

The analysis of this aim focused on using generalized estimating equations (GEE) to examine how patient, caregiver, provider, communication, and asthma control medication characteristics was associated with: caregivers reported their child as adherent to their asthma control medications. As discussed above, an adherence score of at least 80% was defined as adherent. Only children who took asthma control medications were included in the Aim 2 analyses.

We constructed a GEE model to test the association of the measured variables to the caregiver-reported adherence variable. The independent variables for this GEE model were: child race, child age, child gender, asthma severity, count of asthma control medications, caregiver education, caregiver gender, whether benefits were discussed during the audio-taped visit, whether risks were discussed during the audio-taped visit, whether side effects were discussed during the audiotaped visit, family income, whether the child was taking only one asthma control medication, provider gender, provider age, provider race, length of visit, whether adherence was discussed during the audio-taped visit, whether the caregiver was married, number of prior visits with the study provider, the reason for the visit, and whether the child was only taking Montelukast.

Specific Aim #3: To examine the association between risk, side effect, and benefit communication and caregiver- and child-reported problems and concerns about asthma medication side effects one month after the audiotaped medical visit.

H9: Caregivers are less likely to report problems and concerns about side effects with their child's asthma medications if risks were discussed during the medical visit.

H10: Caregivers are less likely to report problems and concerns about side effects with their child's asthma medications if the asthma control medication does not contain an inhaled corticosteroid.

H11: Children are less likely to report problems and concerns about side effects with their asthma control medications if side effects were discussed during the medical visit.

H12: Children are more likely to report problems and concerns about side effects with their asthma control medications if benefits were discussed during the medical visit.

To accomplish this aim, there was a single variable on both the child home visit interview and the caregiver home visit survey that asked how much concern or fear that children and caregivers had of the asthma control medication causing side effects. A plot of the variable revealed a large proportion of "None" answers for this question. The decision was then made to collapse the three categories into a dichotomous variable, where 1=a little or a lot of concern about side effects or 0=no concern about side effects.

Finally, GEE models were constructed to test the association between patient, caregiver, provider, medication, and communication characteristics on caregiver- and child-report

of a problem/concern of side effects of asthma control medication(s). The dependent variable in hypotheses nine and ten was caregiver report of fear/concern of side effects and the dependent variable in hypotheses eleven and twelve was child report of fear/concern of side effects.

The independent variables for the caregiver side effects concern GEE model were: child race, child age, child gender, asthma severity, whether the child was taking an inhaled corticosteroid, caregiver age, caregiver gender, family income, whether side effects were discussed, provider gender, provider age, provider race, length of visit, reason for visit, whether the caregiver was married, risks discussed during the medical visit, benefits were discussed during the medical visit, the number of prior visits with the study provider, whether the child only took Singulair as his/her asthma control medication.

The independent variables for the child side effects concern GEE model were: child race, child age, child gender, asthma severity, whether the child was taking an inhaled corticosteroid, caregiver age, caregiver gender, provider gender, provider age, provider race, length of medical visit, whether the caregiver was married, whether the child was only taking Montelukast as his/her asthma control medication, family income, whether risks were discussed during the medical visit, whether benefits were discussed in the medical visit, whether side effects were discussed, and the reason for the medical visit.

CHAPTER THREE: METHODS FOR QUALITATIVE ANALYSIS (AIM 4)

Overview

This chapter presents the methods used to qualitatively analyze the transcripts of the medical visits for discussions about side effects, risks, and benefits of asthma control medications. Specific Aim 4 is: To qualitatively describe all control medication risks, side effects, and benefits that are discussed during the audiotaped asthma visits.

The chapter is organized into three parts. First, the chapter describes the methods and theory utilized to discern the context of these discussions. Second, the chapter presents the categories that were revealed in the process of the qualitative analysis and the definition for each category, along with some examples of questions and statements that would fit into each category.

Content Analysis of the Medical Visit Transcripts

In this study, to complete the qualitative analysis of discussions about side effects, risks, and benefits, all transcripts were first reviewed to determine the presence of communication about risks, side effects, and benefits.

Content analysis of the transcripts was performed using the following process: processing the raw data, data reduction, data display, conclusion drawing, and then verification

(Strauss and Corbin 1998). The general description of this process is as follows: (1) reading and examining the transcripts to identify questions and statements that convey a single meaning or idea, (2) grouping together and labeling units conforming to themes, (3) data organization, and (4) validating themes.

While completing the coding tool, both coders copied and pasted the text of the entire discussion about side effects, risks, and benefits from the transcripts of the medical visits into the tool. Upon completion of cutting of excerpts from the medical visit transcripts, codes were generated to describe the discovered concepts. The coders carefully reviewed each question and statement to identify the main idea behind the question or statement. By identifying the main topic of each question and statement, both coders began to develop categories. The categories were intended to reflect the main idea of the question and statement. The coders coded 20 of the same transcripts to check for reliability for discussions about side effects, risks, and benefits.

By closely examining the discussion data, both coders were able to identify concepts that were then examined more closely to develop categories; words, phrases, and subject matter that were found to be similar were then grouped into distinct categories. In this analysis, categories described subject matter, such as specific risks that were discussed in the transcripts. As each category was created, a process of constant comparison was employed in assigning new codes, so that text and subject matter that were considered the same were assigned to the same category. This process continued throughout the coding process.

Through category refinement, the definition and conceptualization of the themes of side effect, risk, and benefit communication emerged from the transcripts. Categories were refined until the concepts were not repeated and no new categories were being created, which indicated the analysis reached saturation.

Several steps were undertaken to improve coding reliability and validate the concepts that were discovered in the analysis. First, as previously mentioned, a process of constant comparison was employed so that each new assignment of a code initiated a brief review of previous uses of the same category to ensure that the content of the category addressed the same concept. Next, a second coder was used to double-code 10% (n=30) of the transcripts and assign categories while being blinded to the principal investigator's assignment of categories. The purpose of having a second coder was to check and validate the principal investigator's assignment of categories based around the concepts of the discussions. While none of these actions guarantee valid results, it is believed that the steps taken indicate a rigorous approach to the conduct of the qualitative analysis and improve the validity of the findings.

The goal of the qualitative analysis was to more fully understand the nature of how providers discussed side effects, risks, and benefits of asthma control medications with children and their caregivers. An additional aspect of risk communication that was examined was how comprehensive providers were in the discussions about risks. This

study used Bogardus' dimensions of risk communication (1999) to examine this aspect of risk communication.

Qualitative Analysis of Side Effect Discussions

Questions about Side Effects of Asthma Control Medications

Table 7 presents all of the categories that questions about side effects fell into, along with each category's definition and an example.

There were five categories of questions that were asked about side effects from providers and caregivers. Children did not ask any questions about side effects during these clinic visits. General questions about side effects was the category that was most often used by providers, and caregivers asked one question each from the *Asking for Clarification*, *Bad Taste*, *Weight Gain*, and *Cough* categories.

Table 7: Categories of Questions about Side Effects of Asthma Control Medications

Category	Definition	Example
General	A question that asks about side effects that may have been experienced but does not state a specific side effect	D: "...She didn't have no bad reaction to it or anything like that?"
Asking for Clarification	A question that is a follow-up question of a statement that was previously made about side effects	C: "You don't think so?"
Bad Taste	Questions that were asked about the taste of an asthma control medication	C: "Is it sour?"
Weight Gain	Questions asking if the child was experiencing weight gain from using an asthma control medication	C: "Do you think it's [weight gain] because of the medicine or because he hasn't felt like playing?"
Cough	Questions asking if the child was experiencing cough from a result of using an asthma control medication	C: "Won't be like the cough we have now?"

Statements about Side Effects of Asthma Control Medications

Table 8 presents all of the categories of statements about side effects that were made by participants during the clinic visits.

There were seven categories of statements about side effects during these clinic visits.

The category that was most often used by providers was the *Assurance* category while caregivers made the most statements about *General* side effects and *Headaches*.

Children did make statements about side effects, but always spoke after their caregiver, repeating what the caregiver said about side effects.

Table 8: Categories of Statements about Side Effects of Asthma Control Medications

Category	Definition	Example
Assurance	Statements made to assure that a certain side effect that the child was experiencing was not because of the asthma control medication	D: "'Ah, I wonder if the reason he's tired in the morning is not so much the Advair..."
Thrush	Statements about the child experiencing thrush after taking an asthma control medication	C: "Actually, he was using the Advair every day twice a day like he was supposed to been and he started complaining of a sore throat"
Bad Taste	Statements made about the bad taste of an asthma control medication	P: "It tastes nasty"
Unaware of Side Effects Caused by Medication	Statements made about children experiencing side effects that the provider had not seen or heard before	D: "...and I've just not ever seen that but I guess you know every medicine is different in every kid's body"
Headaches	Statements made about the child experiencing headaches from using an asthma control medication	C: "Well I mean he used to take Singulair, but he got really bad headaches"

Category	Definition	Example
General	Statements made that indicated the child had experienced a side effect, but did not state a specific side effect	C: "We did Advair one time and I didn't like that at all".
Drowsiness	Statements made that indicated the child had experienced drowsiness after using an asthma control medication	C: "Let me tell you something about that, ah, that, that makes him sleepy".

The next section presents the risk discussion categories, along with a definition of each category and an example of each category.

Qualitative Analysis of Risk Discussions

Questions About Risks of Asthma Control Medications

Table 9 presents the categories of questions that were asked about risks during these clinic visits.

Providers asked two questions about risks, one each in the *General* category and the *Steroid Causing Harm* category. When the provider asked questions about risks, the provider used those questions to begin the medication risk discussion. Caregivers asked the most questions in the *Steroid Causing Harm* category and children asked one question each in the *Steroid Causing Harm*, *Anabolic Steroid Risks*, and *Bad Taste* categories.

Table 9: Categories of Questions about Risks of Asthma Control Medications

Category	Definition	Example
Steroid Causing Harm	Questions made that indicated that an asthma control medication might harm a child	P: “It won’t hurt me will it?”
General	Questions made asking about potential risks of an asthma control medication, but did not state a specific risk	C: “Okay, so what are the side effects from the Singulair?”
Drug-Drug Interaction	Questions about the risk of two drug interacting and causing an adverse effect on the child	C: “And it’s safe together [Singulair and anti-histamine]?”
Dose	Questions made about the risks associated with the dose of an asthma control medication being too high	C: “Okay, that’s not too much?”
Probability of Risks Occurring	Questions made asking about the probability of a risk occurring	C: “So it’s not common?”
Anabolic Steroid Risks	Questions asking that compares the risks of anabolic steroids with inhaled corticosteroids	P: “Wait, does steroids um, cut off my fat or something?”.
Bad Taste	Questions that indicated the asthma control medication may taste bad	P: “Is it going to taste better?”.

Statements about Risks of Asthma Control Medications

Table 10 presents the categories of statements about risks of asthma control medications during these clinic visits. **Table 10** also lists the definition of each category as well as one example of each statement.

Overall, there were 16 different categories of statements about the risks of asthma control medications. The category that was most often spoken about was *General* statements about risks, which were statements where a specific risk was not identified. Children did not make any statements about asthma control medication risks during these clinic visits.

Table 10: Categories of Statements about Risks of Asthma Control Medications

Category	Definition	Example
Safety	Statements that indicated the asthma control medication was safe or lacked risks	D: “Those have really got a great safety profile”.
Thrush	Statements made about the possibility of the child getting thrush after using the asthma control medication	D: “Occasionally, people get a little sore throat”.
Bad Taste	Statements that indicated the asthma control medication may taste bad	D: “It doesn’t have that powdery taste”.
Drowsiness	Statements made that indicated the asthma control medication may or may not cause drowsiness	D: “The Singulair can be given at any time of day because it doesn’t cause sleepiness”.
Concerns in Media	Statements about risks stated in popular media, such as newspapers, television, the internet, etc.	D: “Somebody rehashed it on TV and every time it happens I have a kid, ah, family call me up, we’re stopping the medicine because we’re scared of it”.

Category	Definition	Example
Anabolic Steroid Risks	Statements that compare the risks of anabolic steroids with inhaled corticosteroids	D: “Well, remember that the football players are not inhaling steroids, they’re taking shots of testosterone that’s very dangerous”.
Hyper-Activity	Statements made about an asthma control medication causing hyper-activity in children	D: “The only side effect as far as that goes sometimes it hypes them up”.
Steroid Causing Harm	Statements made about an asthma control medication that may or may not cause harm to the child	D: “And there were actually some, with one study showed that increased risk of dying from asthma with people taking Serevent alone”.
Reduction in Growth Velocity	Statements made that indicated an asthma control medication may or may not cause a reduction in growth velocity or final adult height	D: “So you’re not affecting his growth pattern, you will read in the package insert that they say oh, this can affect growth patterns”.
Reduced Immunity	Statements made that an asthma control medication may cause a reduction in immunity	D: “It won’t make him more susceptible to you know, getting infections”.
General	Statements about risks of asthma control medications, but does not state a specific risk	D: “And it tends not to have an effect all over the body because we don’t want that”.
Dose	Statements made about the risk of dosages of an asthma control medication	D: “No, Advair twice a day is fine, you don’t want to do more than twice a day”.
Feels like Taking Albuterol	Statements made that an asthma control medication may make a child feel like (s)he has just taken Albuterol	D: “Occasionally people will feel little bit like they took Albuterol”.

Category	Definition	Example
Long-Term Effects	Statements made about the long-term risks of a child taking an asthma control medication	C: “Yeah because I worry about the long term”.
Drug-Drug Interaction	Statements about the risk of two drugs interacting and causing an adverse effect on the child	D: “Get back on Claritin and then do the Singulair, you can take them both at the same time and it’s no big deal”.
Assurance	Statements made to assure caregivers and children that a condition the child may experience is not related to the child's asthma control medication	D: “It’s not from that [nosebleeds from Singulair]”.
Nosebleeds	Statements made that the child may experience a nosebleed from taking an asthma control medication	C: "But still he gets nosebleeds"

The next section discusses the categories from the qualitative discussions about the benefits of asthma control medications.

Qualitative Analysis of Benefit Discussions

Questions about Benefits of Asthma Control Medications

Table 11 presents the categories of questions that were asked about the benefits of asthma control medications.

There were eight different categories of questions that were asked about the benefits of asthma control medications. The most often discussed category of questions was *Symptom Control/Prevention*. Both caregivers and children asked very few questions about asthma control medication benefits.

Table 11: Categories of Questions about Benefits of Asthma Control Medications

Category	Definition	Example
Symptom Control/Prevention	Questions that asked if the asthma control medication was controlling and preventing asthma symptoms	D: “Advair? How is that working for you?”
Ease of Use	Questions about the ease of use of an asthma control medication or device, including the time it would take for the child to use the asthma control medication or device	D: “How long is it going to take him to do the Pulmicort in the inhaler?”
Quality of Life	Questions made that indicated that the asthma control medication would improve one of the following: asthma symptoms, activity limitation, and negative emotions	D: “Are you worried she is going to get sick and have to come in?”
Adherence	Questions asked about the child's adherence or lack of adherence and the resulting benefit from an asthma control medication	D: “If you take it, does it work?”
Re-iteration	Questions that restated what the caregiver or child said about the control medication benefits	D: “It works good?”
General	Questions that were made that asking specific benefits the asthma control medication would provide	C: “He seems to be doing a lot better with the Singulair than

		without, you know?”
Category	Definition	Example
Teach-Back	Questions using the Teach-Back method of ensuring understanding	D: “To keep it away so you don’t have to use your?”
Potency	Questions that asked about the effectiveness or lack of effectiveness of the asthma control medication	D: “You started two weeks ago, and it’s such a strong medicine that you’re already better right?”

Statements about Benefits of Asthma Control Medications

Table 12 presents the categories of statements that were made about asthma control medication benefits.

Overall, there were 21 categories of statements about the benefits of asthma control medications. The most frequently discussed category was *Symptom Control/Prevention*.

Of note, the *Quality of Life* category was defined as statements that referenced at least one of three concepts: negative emotion, symptoms, and activity limitation. Specifically, these statements indicated that the asthma control medication would improve at least one of the following: asthma symptoms, activity limitation, and negative emotions. The three domains were taken specifically from the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) (Juniper, et. al. 1996), which is a patient and caregiver- reported quality of life measure. It has been shown to be both reproducible and reliable.

Table 12: Statements about Benefits of Asthma Control Medications

Category	Definition	Example
Adherence	Statements about the child's adherence or lack of adherence and the resulting benefit from an asthma control medication	P: "Yeah, usually when I take it, I wait a couple minutes and then I have no more asthma for the rest of the day"
Potency	Statements about the effectiveness or lack of effectiveness of an asthma control medication	P: "Umm, it helps a little bit but not much"
General	Statements made about benefits of asthma control medications but do not name a specific benefit, describing the medication in a positive way	P: "That's why I haven't had as much problems probably since I started taking the Singulair"
Teach-Back	Statements using the Teach-Back method to ensure understanding	P: "To keep it situated"
Multiple Indications	Statements made about an asthma control medication having more than one indication, i.e. control of asthma and allergy symptoms	D: "Singulair is really good for allergies and also asthma preventive medications so I do think Singulair is a good idea"
Decreases Inflammation in Lungs	Statements that indicate the asthma control medication will decrease inflammation in the lungs	D: So we got inflammation, we got spasm, you want to use Pulmicort to get rid of that inflammation"
Consequences of Not Treating	Statements made indicating that not treating the child with an asthma control medication may result in short- and long-term consequences for the child's health	D: "They have long issue problems even in long, later on in life, you know like COPD or emphysema even without smoking ever in their life, you know so there are consequences to not treating"

Category	Definition	Example
Symptom Control/Prevention	Statements indicating that using an asthma control medication would result in improved asthma symptom control and prevention of asthma symptoms	D: “And the Singulair...these are to prevent and control her symptoms”
Quality of Life	Statements made indicating that an asthma control medication would improve one of the following: asthma symptoms, activity limitation, and/or negative emotions	D: “A child should be able to go outside and play as hard and as long as they want and not have to come in and get her inhaler, she should be able to go to a birthday party and blow up balloons just like all the other kids”.
Pulmonary Function	Statements made indicating that an asthma control medication would improve lung function for the child	D: “Okay so that this is (unclear) asthma and improve lung function”
Reduced Need for Rescue Medication	Statements that indicated that an asthma control medication would reduce the child's need for an asthma rescue medication	P: “It helps me not to use it [Albuterol] as much”
Acute Symptoms/Prior to Exercise	Statements about the benefit or lack of benefit an asthma control medication would bestow during acute symptoms and immediately prior to exercise	D: “It does not help in an acute attack, it’s not meant to do that”
Length of Time Medication Works	Statements made indicating the time-frame the asthma control medication would work in the child's body	D: “Advair, the purple disk, when you brush your teeth in the morning, it does have a long acting steroid in it and a long-acting Albuterol so the benefit is it hangs out in the lungs over a 12 hour period”

Category	Definition	Example
Goals of Treatment	Statements made about different and separate benefits in the same statement about the specific goals of treating children with an asthma control medication	D: “And that’s one of the ways how we judge if it is working for you whether you are needing your Albuterol, are you able to sleep through the night without coughing, are you able to exercise, you know run around play without coughing”
Improvement Time-Table	Statements made about the time-frame the caregiver and child could expect to see improvement of asthma symptoms, asthma control, and prevention of symptoms	D: “Give it a good try for four weeks and I really think you will find it is well worth it”
Ease of Use	Statements about the low difficulty of the use of an asthma control medication or device; Statements could also include the time it would take for a child to take a dose of the medication	D: “Well let’s do the Claritin, the Flonase, and the Singulair because that’s as easy as it gets”
Dose	Statements about how well the asthma control medication works at different dosages	D: “Well the interesting thing about Advair (unclear) is there is a dose at which you don’t get much of a response after you get there”
Prevention of Bad Asthma Outcomes	Statements made about asthma control medications preventing bad asthma outcomes and referenced at least one of the following outcomes: missing school days, emergency room visits, hospitalizations from asthma, pulmonary function testing, and chronic asthma exacerbations	D: “That medicine has saved a lot of people from being sick and having to go to the emergency room and all that sort of stuff”.
Inhalation Technique	Statements about the asthma control medication benefit that was dependent on the child's inhalation technique	D: “Yeah it won’t work if you don’t do it right so you’ve got to do it the right way”

Category	Definition	Example
Anticipating Benefit	Statements about anticipating benefits from using an asthma control medication	C: “It seems like a really good direction to go in because...when the steroids were in her...she had really good health”.
Bronchitis	Statements that indicated that an asthma control medication has improved a child's bronchitis symptoms	C: “Well he hasn’t had anything to do with bronchitis since May of last year”

The next chapter describes the results from the quantitative analysis.

CHAPTER FOUR: QUANTITATIVE RESULTS

Children with Asthma and Caregiver Characteristics of Total Sample

Patient characteristics for the full sample of 295 children are presented in **Table 13**.

Approximately 59% (n=173) of the children's visits were asthma-related. The average age of children is 11.1 (SD=2.4; range 8-16). The majority of children were male (54%).

Most patients were classified as having moderate-severe persistent asthma (72%).

Almost all patients had some type of health insurance, with Medicaid as the most prevalent type of insurance (52%). Only 4.1% of children were of Hispanic origin. The number of prior visits with the study provider had large variability, with a mean of 11.1 (SD=11.5; range 0-70). Finally, almost one-third of children (n=83) reported a problem or concern about side effects of their asthma control medication one month after the medical visit.

Table 13: Characteristics of Children with Asthma in Total Sample (N=295)

Characteristics	Percentage (N)
Age, mean (standard deviation) (range)	11.1 (2.4) (8-16)
Child Gender-Male	53.7 (153)
Race	
Black	30.1 (89)
White	61.5 (182)
American Indian/Alaskan Native	10.1 (30)
More than One Race	10.1 (31)
Native Hawaiian or Other Pacific Islander	1.0 (3)
Asian	0.3 (1)
Other	4.7 (14)
Hispanic	4.1 (12)
Asthma Severity	
Mild Persistent	28.0 (83)
Moderate-Severe Persistent	72.0 (213)
Medical Insurance	
None	1.0 (3)
Private	26.5 (78)
Medicaid	52.0 (153)
NC Health Choice	17.7 (52)
Other	2.7 (8)
Reason for Visit-Asthma	59.0 (173)
Number of prior visits with study provider, mean (standard deviation) (range)	11.1 (11.5) (0-70)
Child-reported Problems and Concerns About Side Effects of Asthma Control Medication	32.6 (83)

Table 14 shows the caregiver's characteristics from the sample. The majority of caregivers were female (85.8%) and were married (58.4%). The mean age of caregivers in this sample was 41 years (SD=8.4; range=26-80). The mean years of education for caregivers were 12.8 years (SD=2.5; range=2-20). Most caregivers had an annual income between \$30,000 and \$49,999 (23.9%).

Caregiver-reported average adherence for children taking control medications was 84.6% (standard deviation=25.9) with a range of 0-100. Caregivers reported that almost 60% of children had an average adherence score of at least 80%, classified as adherent to their asthma control medication(s). About 37% (n=96) of caregivers reported a problem or concern about side effects of their child's asthma control medication one month after the audio-taped medical visit.

Table 14: Characteristics of Caregivers of Children with Asthma in Total Sample (N=295)

Caregiver Characteristics	Percentage (N)
Caregiver Age , mean (standard deviation) (range)	41.0 (8.4) (26-80)
Caregiver Gender-Female	85.8 (253)
Marital Status	
Never Married	16.4 (48)
Married	58.4 (171)
Widowed	3.1 (9)
Separated	9.6 (28)
Divorced	12.6 (37)
Years of Education , mean (standard deviation) (range)	12.8 (2.5) (2-20)
Family Income	
Less Than \$10,000	21.5 (62)
Between \$10,000 and \$19,999	20.1 (58)
Between \$20,000 and \$29,999	13.8 (40)
Between \$30,000 and \$49,999	23.9 (69)
Between \$50,000 and \$69,999	8.7 (25)
\$70,000 or More	12.1 (35)
Caregiver-Reported Child Adherence Score , mean (standard deviation) (range)	84.6 (25.9) (0-100)
Child Adherence Score of at Least 80%	59.2 (138)
Caregiver-Reported Problem/Concern About Side Effects of Asthma Control Medication	37.2 (96)

Provider Characteristics

The characteristics for the full sample of 35 providers are presented in **Table 15**. The majority of providers were female (51.4%) and classified as physicians (88.6%). The mean age for providers was 44 years (SD=9.3; range=29-69).

Table 15: Characteristics of Medical Providers (N=35)

Characteristics of Provider	Percentage (N)
Provider Gender- Female	51.4 (18)
Provider Type	
Physician	88.6 (31)
Physician Assistant/Nurse Practitioner	8.6 (3)
Nurse	2.9 (1)
Age, mean (standard deviation) (range)	44 (9.3) (29-69)

Medical Visit Communication Characteristics

This section describes the characteristics of the office visit, specifically the communication variables and associated variables that came from the coding of the audiotape transcripts. Each of the following is described separately: side effects discussion, risk discussion, and benefit discussion. Information on the communication variables and associated variables are presented in **Table 16** for the entire sample.

Table 16: Medical Visit Communication Characteristics (N=295)

Medical Visit Communication Characteristics	Percentage (N)
Length of Visit with Provider in seconds , mean (SD) (range)	915 (509.9) (139-2743)
Number of Control Medications Discussed , mean (standard deviation) (range)	1.3 (0.8) (0-4)
Second Caregiver in Room	7.4 (22)
Side Effects Discussed	4.1 (12)
Caregiver Starts Side Effect Discussion	2.0% (6)
Provider Starts Side Effect Discussion	2.0% (6)
Risks Discussed	15.9 (47)
Caregiver Starts Risk Discussion	4.4 (13)
Provider Starts Risk Discussion	10.5 (31)
Child Starts Risk Discussion	1.0 (3)
Benefits Discussed	47.3 (140)
Caregiver Initiates Benefit Discussion	5.4 (16)
Provider Initiates Benefit Discussion	87.1 (122)
Child Initiates Benefit Discussion	0.7 (2)
Adherence to Control Medication Discussed	46.8 (138)

The mean length of visits with providers was 915 seconds (SD=509.9) with a range of 139 seconds to 2743 seconds. Therefore the average visit length was 15 minutes, with a range of approximately two minutes to approximately 46 minutes. The mean number of asthma control medications discussed was 1.3 (standard deviation=0.8) with a range of 0-4. Seven percent of medical visits included more than one caregiver (n=22).

Side effects of asthma control medications were discussed during approximately 4.1% (n=12) of the visits. Asthma control medication risks were discussed during approximately 16% (n=47) of the visits. The benefits of asthma control medications were discussed during 47.3% (n=140) of the visits. There was a discussion about adherence to asthma control medications during approximately 47% (n=138) of the visits.

Both risks and benefits were discussed together during approximately 11.9% (n=35) of medical visits. Side effects and benefits were discussed together during approximately 1.7% (n=5) of medical visits. There were no visits where risks and side effects were discussed together without a discussion of benefits. Finally, approximately 0.7% (n=2) of medical visits included a discussion of side effects, risks, and benefits together.

Characteristics of Medications Discussed During Medical Visits

Table 17 shows the percentage of medical visits where each asthma control medication was discussed. Singulair was the asthma control medication that was most often discussed. More than 44% (n=132) of medical visits included a discussion about Singulair. Advair was the next most often discussed asthma control medication, with 42.4% (n=125) of medical visits in which it was discussed. More than 16% (n=48) of medical visits did not include any discussion about asthma control medications.

Table 17: Medications Discussed during Medical Visits (N=295)

Medications Discussed in Medical Visits	Percentage (N)
Singulair	44.7% (132)
Advair	42.4% (125)
Pulmicort	15.9% (47)
Flovent	14.9% (44)
Asmanex	4.4% (13)
Qvar	1.0% (3)
Symbicort	1.0% (3)
Serevent	0.3% (1)
Number of Visits Where An Asthma Control Medication was not Discussed	16.3% (48)
Children Taking Singulair Plus Inhaled Corticosteroid	29.2% (86)
Children Only Taking Singulair	11.9% (35)

Of the 295 patients in the study, 25% of children were prescribed at least one new asthma control medication during the medical visits. The mean number of asthma control medications that each child was taking or prescribed was 1.14 (SD = 0.71), with a range of 0-3. Almost 72% of children were currently taking or had at least one inhaled corticosteroid prescribed. Approximately 12% (n=35) of children only took Singulair as their asthma control medication after the medical visit. Approximately 29% of children took Singulair and an inhaled corticosteroid as their asthma control medications.

Bivariate Results Among Independent Variables

Table 18 presents the bivariate associations between the independent variables as a correlation matrix. White children were significantly more likely to see White providers ($r=0.21$, $p=0.0004$). Children taking inhaled corticosteroids were significantly more likely to have Moderate/Severe Persistent Asthma ($r=0.32$, $p<0.0001$). Children who were taking inhaled corticosteroids were significantly more likely to have a higher count of medications ($r=0.62$, $p<0.0001$). Adherence was significantly more likely to be discussed when the child took a higher number of asthma control medications ($r=0.33$, $p<0.0001$), when the child was taking an inhaled corticosteroid ($r=0.34$, $p<0.0001$), and when the visit was for asthma ($r=0.20$, $p=0.0004$).

Table 18: Correlation Matrix Between Independent Variables (N=295)

	White	Child Age	Child Gender	Asthma Severity-Moderate /Severe Persistent	Income Above \$20,000	# Asthma Medications	Patient Taking ICS	Length of Visit	Adherence Discussed-Yes	Asthma Visit	# Prior Visits	Child Taking Singulair Only-Yes
White	1.00											
Child Age	-0.03	1.00										
Child Gender-Female	0.17*	0.05	1.00									
Asthma Severity-Moderate/ Severe Persistent	-0.04	0.09	0.01	1.00								
Income Above \$20,000	0.23	0.01	-0.01	-0.08	1.00							
#Asthma Medication	-0.08	-0.17*	-0.06	0.27*	-0.10	1.00						
Patient Taking ICS	-0.01	-0.11*	-0.03	0.32*	-0.04	0.62*	1.00					
Length of Visit	-0.01	0.01	0.00	0.07	0.10	0.11	0.12*	1.00				
Adherence Discussed	0.00	0.04	-0.06	0.15*	-0.08	0.33*	0.34*	0.02	1.00			
Asthma Visit	-0.22*	-0.12*	-0.10	0.13*	-0.13*	0.32*	0.28*	-0.03	0.20*	1.00		
# Prior Visits	0.02	-0.13*	-0.05	0.02	-0.01	-0.02	0.03	-0.04	0.02	-0.03	1.00	

	White	Child Age	Child Gender	Asthma Severity= Moderate/ Severe Persistent	Income Above \$20,000	# Asthma Medications	Patient Taking ICS	Length of Visit	Adherence Discussed- Yes	Asthma Visit	# Prior Visits	
Child Taking Singulair Only	-0.04	0.01	-0.09	-0.21*	0.02	-0.09	-0.59*	0.03	-0.05	-0.01	-0.08	1.00
Child Taking 1 Asthma Control Medication	0.06	0.01	-0.13*	-0.08	0.10	-0.21*	0.13*	0.07	0.11*	0.03	0.07	0.32*

*p<0.05

Bivariate Results Among Independent Variables and Outcome Variables

Table 19 presents the correlation matrix between the independent and dependent variables. Each independent variable is listed as rows in **Table 19** and the outcome variables are listed in the columns of **Table 19**. Below also discusses bivariate results using t-tests or Pearson chi-squares if appropriate.

Children whose visits included a discussion about side effects were younger on average (9.6 years old versus 11.0 years old) than children whose visits did not include a discussion about side effects ($t=-2.02$, $p=0.04$).

Risks were significantly more likely to be discussed when: the child took a higher number of asthma control medications on average (1.45 versus 1.08, $t=4.28$, $p<0.0001$), when the child was taking or prescribed an inhaled corticosteroid (Chi-square=5.2, $p=0.02$), and when the visit was longer on average (1335.3 seconds versus 858.2 seconds, $t=6.01$, $p<0.0001$).

Benefits were significantly more likely to be discussed when: the child was younger on average (10.7 years versus 11.4 years, $t=-2.53$, $p=0.01$), the child was classified as having moderate/severe persistent asthma (Chi-square=4.92, $p=0.03$), when the child took a higher number of asthma control medications on average (1.4 versus 0.9, $t=6.09$, $p<0.0001$), when the child was taking or prescribed an inhaled corticosteroid during the visit (Chi-square=39.11, $p<0.0001$), when the visit was longer on average (988.3 seconds versus 849.7 seconds, $t=2.35$, $p=0.02$), when control medication adherence was discussed

(Chi-square=17.66, $p<0.0001$), and when the visit was asthma-related (Chi-square=8.88, $p=0.003$).

Caregivers were significantly more likely to report their child as at least 80% adherent to their asthma control medications when: the child took a higher number of asthma control medications on average (1.3 versus 1.1, $t=1.97$, $p=0.05$), when the child was taking or prescribed an inhaled corticosteroid (Chi-square=4.11, $p=0.04$), when the visit was longer on average (991 versus 810.2, $t=2.84$, $p=0.01$), and when the child had seen the provider (s)he saw during the study more times on average (13.3 versus 8.4, $t=3.2$, $p=0.00$).

Caregivers were significantly more likely to report a problem/concern about side effects one month after the audiotaped medical visit when the child had seen the provider (s)he saw during the study less times on average (8.4 versus 13.1, $t=-3.52$, $p=0.000$).

Children were significantly more likely to report a problem/concern about side effects one month after the audiotaped medical visit when: the child was Non-White (Chi-square=4.27, $p=0.04$), when the child was not taking an inhaled corticosteroid (Chi-square=4.58, $p=0.03$), when the caregiver was not married (Chi-square=6.24, $p=0.01$), and when the child was only taking Singulair as their asthma control medication (Chi-square=5.08, $p=0.02$).

Table 19: Correlation Matrix Between Independent and Outcome Variables

	Side Effects Discussed-Yes	Risks Discussed-Yes	Benefits Discussed-Yes	Caregiver Adherence of At Least 80%-Yes	Caregiver Concern About Side Effects-Yes	Child Concern About Side Effects-Yes
Child Race-White	0.08	-0.03	0.01	0.01	-0.03	-0.13*
Child Age	-0.13*	-0.06	-0.15*	-0.09	0.02	-0.06
Child Gender-Female	-0.05	-0.07	-0.10	0.04	0.05	0.02
Asthma Severity-Moderate/Severe Persistent	0.02	0.07	0.13*	0.04	0.06	-0.02
Caregiver Education	0.04	0.01	0.03	0.05	0.10	0.09
Caregiver Gender-Female	0.08	-0.03	-0.04	0.03	0.09	0.07
Income of At Least \$20,000	0.04	0.00	0.03	-0.03	0.05	0.04
Count of Asthma Medications	-0.04	0.19*	0.33*	0.13*	0.02	-0.07
Patient Taking Inhaled Corticosteroids-Yes	0.05	0.23*	0.36*	0.13*	0.07	-0.13*
Provider Gender-Female	0.04	0.04	-0.04	-0.09	-0.01	-0.11
Provider Race-White	-0.05	-0.08	0.05	0.02	-0.10	-0.01
Provider Age	-0.01	-0.09	-0.01	0.03	0.04	0.03
Length of Visit	0.01	0.36*	0.14*	0.18*	0.10	-0.04

	Side Effects Discussed-Yes	Risks Discussed- Yes	Benefits Discussed-Yes	Caregiver Adherence of At Least 80%- Yes	Caregiver Concern About Side Effects-Yes	Child Concern About Side Effects-Yes
Caregiver Married -Yes	0.07	0.07	0.04	-0.05	-0.03	-0.16*
Adherence Discussed-Yes	-0.06	0.00	0.24*	0.03	0.07	0.08
Reason for Visit- Asthma	0.10	0.06	0.17*	0.01	-0.01	0.06
Number of Prior Visits	0.09	-0.05	0.02	0.21*	-0.20*	0.00
Child Taking Singulair Only- Yes	0.03	-0.10	-0.07	-0.08	-0.10	0.14*
Child Taking 1 Asthma Control Medication-Yes	0.09	-0.08	-0.04	-0.06	-0.03	0.08

*p<0.05

Multivariate Analyses

Specific Aim #1: To examine the association between provider, caregiver, and child characteristics and communication about risks, side effects, and benefits of asthma control medications during audiotaped pediatric visits.

This section describes the results of the examination of the patient, caregiver, provider, medication, and visit characteristics that are associated with communication about asthma control medication risks and benefits. This section also describes the results of the examination of caregivers who reported their child as 80% or more adherent, caregiver-reported problems/concerns about side effects, and child-reported problems/concerns about side effects of asthma control medications. Results in this section are based upon the patients for which data were available on the outcome variables.

Communication about Medication Side Effects by Child, Caregiver, Provider, Medication, and Other Communication Characteristics

H1: Discussions of asthma control medication side effects will be more likely to be discussed when there is more than one caregiver is present during the audiotaped medical visit.

Communication about Asthma Control Medication Side Effects

There was insufficient variation to run a GEE model predicting side effect discussion, because approximately 4% of medical visits included a discussion of side effects.

Hypothesis one was rejected based on the bivariate results for the side effect discussion variable (Fisher's Exact Test $p=0.62$). This finding should be interpreted with caution however, because discussions of side effects rarely occurred.

Communication about Medication Risks by Child, Caregiver, Provider, Medication, and Other Communication Characteristics

H2: Discussions of asthma control medication risks will be more likely to occur when caregivers have lower incomes.

H3: Discussions of asthma control medication risks will be more likely to occur when there is more than one caregiver present during the audio-taped medical visit.

H4: Discussions of asthma control medication risks will be more likely to occur when caregivers are less educated.

Table 20 shows the results from the GEE with the Risk Discussion variable as the dependent variable. Hypotheses two through four were all rejected based on the *Risk Discussion* GEE model's results. The variable that measured caregiver income less than \$20,000 had an adjusted beta=0.12, $p=0.79$. The variable that measured a second caregiver in the medical visit had an adjusted beta=-0.10, $p=0.90$. The variable that measured caregiver education had an adjusted beta=-0.15, $p=0.07$.

Risks were significantly more likely to be discussed during visits with children who were taking or prescribed an inhaled corticosteroid (Adjusted Beta=2.94, $p=0.001$) and when the length of the visit was longer (Adjusted Beta=0.002, $p<0.0001$).

Table 20: GEE Predicting Risk Discussions Results (N=255)

Independent Variable	Adjusted Beta	Robust SE	p-value
Child Race-White	-2.04	1.68	0.21
Child Age	-0.05	0.11	0.66
Child Gender-Female	-0.63	0.55	0.25
Asthma Severity-Moderate-Severe Persistent	-0.01	0.48	0.98
Child Taking an Inhaled Corticosteroid	2.94*	0.90	0.001
Caregiver Age	-0.02	0.02	0.40
Caregiver Gender-Female	0.05	0.47	0.92
Caregiver Education	-0.15	0.08	0.07
Family Income of at Least \$20,000	0.12	0.46	0.79
Provider Gender-Female	0.00	0.51	1.00
Provider Age	-0.02	0.02	0.31
Provider Race-White	-1.20	0.81	0.14
Length of Visit	0.002**	0.00	<0.0001
Adherence Discussed	-0.39	0.48	0.41
Second Caregiver in Room	-0.10	0.77	0.90
Reason for Visit-Asthma	0.50	0.56	0.37
Caregiver Married	0.23	0.49	0.64
Number of Prior Visits with Study Provider	-0.02	0.02	0.22
Racial Concordance for Child and Provider	2.20	1.69	0.19

*p<0.05; **p<0.0001

Communication about Medication Benefits by Child, Caregiver, Provider, Medication
and Other Communication Characteristics

H5: Discussions of asthma control medication benefits will be more likely to be discussed when the child has moderate/severe persistent asthma.

Table 21 shows the results from the GEE with the Benefit Discussion variable as the dependent variable. Hypothesis five was rejected based on the *Benefit Discussion* GEE model. The variable that measured the child's asthma severity had an Adjusted Beta=0.22, p-value=0.47. This could have occurred because child age and medication adherence being discussed may account for more of the variance when all three are included in the same model.

Benefits were significantly more likely to be discussed when the child was younger (Adjusted Beta=-0.19, p=0.012), when the child was taking or prescribed an inhaled corticosteroid (Adjusted Beta=1.20, p=0.0004) and when control medication adherence was discussed during the visit (Adjusted Beta=1.00, p=0.002).

Table 21: GEE Predicting Benefit Discussions Results (N=255)

Independent Variable	Adjusted Beta	Robust SE	p-value
Child Race-White	-0.002	0.65	1.00
Child Age	-0.19*	0.07	0.01
Child Gender-Female	-0.39	0.33	0.23
Asthma Severity-Moderate-Severe Persistent	0.18	0.28	0.53
Child Taking an Inhaled Corticosteroid	1.20*	0.34	0.0004
Caregiver Age	-0.01	0.02	0.44
Caregiver Gender-Female	-0.76	0.46	0.10
Caregiver Education	-0.10	0.05	0.07
Family Income of at Least \$20,000	0.30	0.30	0.32
Provider Gender-Female	0.18	0.52	0.73
Provider Age	0.01	0.02	0.78
Provider Race-White	0.42	0.62	0.50
Length of Visit	0.00	0.00	0.19
Adherence Discussed	1.00*	0.32	0.002
Second Caregiver in Room	.056	0.48	0.24
Reason for Visit-Asthma	0.31	0.32	0.33
Caregiver Married	0.12	0.36	0.74
Number of Prior Visits with Study Provider	-0.00	0.01	0.65
Racial Concordance for Child and Provider	-0.06	0.71	0.93

*p<0.05

Specific Aim #2 Results

Caregiver-Reported Adherence of At Least 80%

H6: Children are more likely to report being adherent to their asthma control medications if risks were discussed in the medical visit.

H7: Children are more likely to report being adherent to their asthma control medications when the control medication was only Singulair.

H8: Children are more likely to report being adherent to their asthma control medications when the child is taking only one asthma control medication.

Table 22 presents the results of the GEE model for caregiver-reported adherence of at least 80%. As previously stated, Hypotheses six through eight were all rejected based on the GEE results. The variable that measured whether risks were discussed had an adjusted beta=0.39 with a p-value=0.38. The variable that measured whether Singulair was the child's only asthma medication had an adjusted beta=-0.53 with a p-value=0.19. Finally, the variable that measured whether children were on one asthma control medication had an adjusted beta=0.13 and a p-value=0.69.

Caregivers were significantly more likely to report their child being 80% or more adherent to their asthma control medications when the medical visit was longer (Adjusted Beta=0.001, p=0.003), when the child took a higher number of asthma control medications (Adjusted Beta=0.72, p=0.002), and when the child had more prior visits with the study provider (Adjusted Beta=0.05, p=0.007).

Table 22: GEE Results Predicting Caregiver-Reported Adherence of at least 80% (N=214)

Independent Variables	Adjusted Beta	Robust SE	p-value
Child Race-White	0.01	0.35	0.99
Child Age	-0.05	0.06	0.46
Child Gender-Female	0.22	0.28	0.43
Asthma Severity-Moderate-Severe Persistent	-0.00	0.40	0.99
Count of Asthma Control Medications	0.72*	0.23	0.002
Caregiver Education-Years	0.03	0.07	0.63
Caregiver Gender-Female	0.20	0.51	0.69
Benefits Discussed	-0.65	0.42	0.13
Risks Discussed	0.39	0.45	0.38
Family Income of At Least \$20,000	-0.34	0.36	0.35
Side Effects Discussed	0.90	0.65	0.17
Child Taking 1 Asthma Control Medication	0.13	0.32	0.69
Provider Gender-Female	--0.54	0.38	0.15
Provider Age	0.02	0.02	0.35
Provider Race-White	0.18	0.44	0.68
Length of Visit	0.001*	0.00	0.003
Adherence Discussed	-0.15	0.35	0.67
Caregiver Married	-0.55	0.45	0.23
Number of Prior Visits with Study Provider	0.05*	0.02	0.007
Reason for Visit-Asthma	-0.24	0.38	0.54
Child only taking Montelukast	-0.53	0.41	0.19

*p<0.05

Specific Aim #3 Results

Caregiver-Reported Problems and Concerns about Side Effects of Asthma Control

Medications

H9: Caregivers are less likely to report problems and concerns about side effects with their child's asthma medications if risks were discussed during the medical visit.

H10: Caregivers are less likely to report problems and concerns about side effects with their child's asthma medications if the asthma control medication does not contain an inhaled corticosteroid.

Table 23 presents the results of the GEE model where caregivers reported a problem and concern about their child's asthma control medication. Again, Hypotheses nine and ten were both rejected based on the GEE results. The variable that measured discussions of medication risk had an adjusted beta=-0.08, $p=0.85$. The variable that measured whether children were taking an inhaled corticosteroid had an adjusted beta=-0.16, with a p -value=0.70.

Caregivers were significantly more likely to report a problem and concern about the side effects of their child's asthma medication when the child had fewer prior visits with the study provider (Adjusted Beta=-0.04, $p=0.005$).

Table 23: GEE Results Predicting Caregiver-reported Problems and Concerns with Side Effects of Child's Asthma Control Medication (N=215)

Independent Variable	Adjusted Beta	Robust SE	p-value
Child Race-White	-0.20	0.43	0.64
Child Age	0.02	0.06	0.73
Child Gender-Female	0.18	0.29	0.52
Asthma Severity-Moderate-Severe Persistent	0.23	0.34	0.50
Child Taking an Inhaled Corticosteroid	--0.13	0.45	0.77
Caregiver Age	0.00	0.02	0.94
Caregiver Gender-Female	0.55	0.57	0.34
Family Income of at Least \$20,000	0.31	0.36	0.39
Side Effects Discussed	-0.15	0.53	0.78
Provider Gender-Female	-0.14	0.44	0.76
Provider Age	0.01	0.02	0.67
Provider Race-White	-0.47	0.43	0.27
Length of Visit	0.00	0.00	0.28
Reason for Visit-Asthma	0.02	0.32	0.94
Caregiver Married	-0.32	0.32	0.32
Risks Discussed	-0.03	0.44	0.94
Benefits Discussed	0.30	0.30	0.32
Number of Prior Visits with Study Provider	-0.04*	0.02	0.005
Child Taking Only Montelukast as Asthma Control Medication	-0.66	0.54	0.22

*p<0.05

Child-Reported Problems and Concerns about Side Effects of Asthma Control

Medications

H11: Children are less likely to report problems and concerns about side effects with their asthma control medications if side effects were discussed during the medical visit.

H12: Children are more likely to report problems and concerns about side effects with their asthma control medications if benefits were discussed during the medical visit.

Table 24 presents the results of the GEE model where children reported a problem and concern about their asthma control medication. Hypotheses eleven and twelve were rejected based on the GEE results. The variable that measured discussions about side effects had an adjusted beta=-0.91 and a p-value=0.23. The variable that measured discussions about benefit had an adjusted beta=0.32 with a p-value=0.27.

Children were significantly more likely to report a problem and concern about side effects of their asthma control medication when the caregiver was not married (Adjusted Beta=-1.08, p=0.006), when the child did not take an inhaled corticosteroid (Adjusted Beta=-0.94, p=0.026), and when the provider was male (Adjusted Beta=-0.61, p=0.02).

Table 24: GEE Results Predicting Child-reported Problems and Concerns about Side Effects of Asthma Control Medications (N=240)

Independent Variable	Adjusted Beta	Robust SE	p-value
Child Race-White	-0.17	0.28	0.56
Child Gender-Female	0.28	0.30	0.35
Child Age	-0.07	0.07	0.33
Asthma Severity-Moderate-Severe Persistent	0.43	0.26	0.10
Child Taking an Inhaled Corticosteroid	-0.94*	0.42	0.026
Caregiver Age	-0.01	0.02	0.56
Caregiver Gender-Female	0.61	0.60	0.31
Provider Gender-Female	-0.61*	0.27	0.02
Provider Age	-0.00	0.01	0.83
Provider Race-White	0.02	0.42	0.96
Length of Visit	-0.00	0.00	0.66
Caregiver Married	-1.08	0.40	0.006
Risks of Asthma Control Medication Discussed	0.25	0.35	0.46
Benefits of Asthma Control Medicaid Discussed	0.32	0.29	0.27
Side Effects Discussed	-0.91	0.76	0.23
Child Only Taking Montelukast as Asthma Control Medication	0.86	0.57	0.13
Family Income of Least \$20,000	0.60	0.36	0.09
Reason for Visit-Asthma	0.050	0.29	0.09

*p<0.05

CHAPTER FIVE: QUALITATIVE RESULTS (AIM 4)

Overview

This chapter presents the results of the qualitative analysis of the audiotape recorded medical visits. The results of this chapter specifically refer to Aim 4 which stated the objective was: to qualitatively describe all control medication risks, side effects, and benefits that are discussed during the audiotaped asthma visits. This analysis focused on the actual content of the discussions about asthma control medication side effects, risks, and benefits. The chapter is organized into three sections, presenting the frequency of the discussions as well as examples of the actual discussion content for each section. First, the results will show the extent and content of discussions about asthma control medication side effects. Second, the results will present the extent and the content of the discussions about asthma control medication risks. This section will also present the results of how often providers addressed each of Bogardus' dimensions of risk. Finally, the third section will present the results of asthma control medication benefits.

Side Effects of Asthma Control Medications Discussion Content

This section describes the results of the analysis of the content of communication about asthma control medication side effects in the 4% (n=12) of medical visits where side effects were discussed.

Provider Questions about Side Effects of Asthma Control Medications

Under the major category questions about side effects from providers, two categories emerged from the content analysis of the medical visit communication. The first category was *General* questions about if the child/patient had experienced any side effects from the asthma control medication. The second category was *Asking for Clarification* from caregivers and children. The sections below describe the categories in detail and provide illustrative excerpts from the transcripts. Actual transcript data and direct participant quotes are used as much as possible. To preserve confidentiality, all direct quotations from the transcripts are presented by noting whether it is a provider, caregiver, patient, or other family member speaking. All proper names of people and places are omitted and a generic Dr ____ was used to replace any mention of a specific doctor's name.

Table 25 presents the extent to which providers asked caregivers and children questions about side effects of asthma control medications. Four visits included providers asking *General* questions and one visit where a provider asked *Clarification* questions. The range for provider questions about side effects was 0-3. In total, providers asked questions about side effects during 2% (n=5) of medical visits and asked a total of 7 questions. **Table 26** presents the actual questions that providers asked about side effects.

Table 25: Percentage of Visits Where Providers Asked Questions about Side Effects of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
General	1.4% (4)
Asking for Clarification	0.3% (1)
Bad Taste	0 (0)
Weight Gain	0 (0)
Cough	0 (0)

Table 26: Actual Provider Questions about Side Effects of Asthma Control Medications

Category	Actual question from provider
General	No problems with that?
	No problems with that?
	She didn't have no bad reaction to it or anything like that?
	So you emailed me that you are concerned that ___ Singulair gave him kind of these funky side effects?
Asking for Clarification	It does?
	Um, does it really slow him down a lot?
	I mean like, in the mornings too?

Provider Statements about Side Effects of Asthma Control Medications

Under the major category statements about side effects from providers, four categories emerged from the analysis: *Assurance*, *Thrush*, *Bad Taste*, and *Unaware of Side Effects Caused by Medication*.

Table 27 presents the frequencies of provider statements about side effects of asthma control medications. Three providers made *Assuring* statements, one provider made statements about *Thrush*, two providers made *Taste* statements, and one provider made *Unaware* statements. The range of provider statements about side effects was 0-4. In total, providers made statements about side effects during 2% (n=7) of visits and made a total of 14 statements.

Table 27: Percentage of Visits Where Providers Made Statements about Side Effects of Asthma Control Medication (N=295)

Category	Percentage of Visits (N)
Assurance	1.0% (3)
Thrush	0.3% (1)
Bad Taste	0.7% (2)
Unaware of Side Effects Caused by Medication	0.3% (1)
Headaches	0 (0)
General	0 (0)
Drowsiness	0 (0)

Table 28 presents examples of the actual statements that providers made about side effects.

Table 28: Actual Provider Statements about Side Effects of Asthma Control Medications

Category	Actual statement from Provider
Assurance	Not related to her asthma medicine.
	I don't think it's the medicine
	There shouldn't be anything in there to make him...
	Ah I wonder if the reason he's tired in the morning is not so much the Advair, um, I'd try it this summer...when he's at home
	Yeah I don't think it's the Advair then because that would happen every time you gave it.
	No I don't, maybe related to allergies or something like that
Thrush	Then you need to make sure that you rinse out your mouth after you use the Advair, right afterwards.

Category	Actual Statement from Provider
Bad Taste	Ok, so big long breath, it tastes worse, but the longer you go the better it tastes
	Yea, but if you did it really short, it'll taste even worse
	Well you shouldn't be able to taste it at all anyway, it should be tasteless
	...sometimes if you get a little of the powder inside of your mouth it's almost grapefruity, kind of sour
Unaware of Side Effects Caused By Medication	and I've just not ever seen that but I guess you know every medicine is different in every kid's body

Caregiver Questions about Side Effects of Asthma Control Medications

This section describes the results of the analysis of the communication content about asthma control medication side effects from caregivers. Under the major category questions about side effects from caregivers, four categories emerged from the content analysis of caregiver questions during the medical visit: *Clarification*, *Bad Taste*, *Weight Gain*, and *Cough*.

Table 29 presents the frequencies of caregiver questions about side effects of asthma control medications. There was one visit where a caregiver asked a *Clarification* question, one visit where the caregiver asked a question about *Bad Taste*, one visit where the caregiver asked if the child was experiencing weight gain as a side effect and one visit where the caregiver asked if the child was experiencing cough as a side effect of the asthma control medication. The range for caregiver questions about side effects was 0-1. In total, caregivers asked questions about side effects during 1% (n=4) of clinic visits and a total of four questions were asked by caregivers.

Table 29: Percentage of Visits Where Caregivers Asked Questions about Side Effects of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
General	0 (0)
Asking for Clarification	0.3% (1)
Bad Taste	0.3% (1)
Weight Gain	0.3% (1)
Cough	0.3% (1)

Table 30 presents the actual questions made by caregivers to both providers and children about side effects.

Table 30: Actual Caregiver Questions about Side Effects of Asthma Control Medications

Category	Actual Questions from Caregivers
Clarification	You don't think so? (headaches from control medications)
Bad Taste	Is it sour?
Weight Gain	Do you think it's because of the medicine or because he hasn't felt like playing?
Cough	Won't be like the cough we have now?
Clarification	You don't think so? (headaches from control medications)
Bad Taste	Is it sour?
Weight Gain	Do you think it's because of the medicine or because he hasn't felt like playing?
Cough	Won't be like the cough we have now?

Caregiver Statements about Side Effects of Asthma Control Medications

Under the major category caregiver statements about side effects, four categories emerged from the content analysis of the caregiver statements made during the medical visit: *Headaches*, *General*, *Thrush*, and *Drowsiness*.

Table 31 presents the frequencies of visits where caregivers made statements about side effects. There were three visits in which caregivers made statements about the child experiencing *Headaches* after taking an asthma control medication, three visits in which caregivers made statements about *General* statements about side effects, one visit in which a caregiver made a statement about *Thrush*, and one visit in which a caregiver made statements about *Drowsiness* from an asthma control medication. The range for caregiver statements was 0-2. In total, caregivers made statements about side effects during 3% (n=8) of clinic visits and a total of ten statements were made by caregivers regarding side effects of asthma control medications.

Table 31: Percentage of Visits Where Caregivers Made Statements about Side Effects of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Assurance	0 (0)
Thrush	0.3% (1)
Bad Taste	0 (0)
Unaware of Side Effects Caused by Medication	0 (0)
Headaches	1.0 (3)
General	1.0 (3)
Drowsiness	0.3% (1)

Table 32 presents the actual statements made by caregivers about side effects.

Table 32: Actual Caregiver Statements about Side Effects of Asthma Control Medications

Category	Actual statements From Caregivers
Headaches	I took his Singulair away, he has not complained to me about headaches
	She gets to many headaches though, it's driving us crazy.
	Well I mean he used to take Singulair but he got really bad headaches
General	I'm interested to see that one of the side effects they mention in this book is (unclear)
	We did Advair one time and I didn't like that at all
	That's the only thing I could pin it on
Thrush	Actually he was using the Advair every day twice a day like he was supposed to been and he started complaining of a sore throat.
Drowsiness	Let me tell you something about that, ah, that, that, that makes him sleepy
	In the morning, like if I give it to him in the morning, ah, you know his teacher complains about you know sluggish or dragging but when I don't give it, I give it to him when he comes home from school and then before he goes to bed he's fine

Children's Questions about Side Effects of Asthma Control Medications

Children did not ask any questions about side effects during these medical visits.

Children's Statements about Side Effects of Asthma Control Medications

Under the major category children statements about side effects, two categories emerged from the analysis of the medical visit transcripts: *Thrush* and *Bad Taste*.

Table 33 presents the extent to which children/patients made statements about side effects during the clinic visits. One clinic visit included a child making a statement about *thrush* and two clinic visits included children making statements about *Bad Taste*. In total, children made statements regarding side effects during 1% (n=2) of clinic visits and children made a total of two statements during the audiotaped medical visits.

Table 33: Percentage of Visits Where Children Made Statements about Side Effects of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Assurance	0 (0)
Thrush	0.3% (1)
Bad Taste	0.3% (1)
Unaware of Side Effects Caused by Medication	0 (0)
Headaches	0 (0)
General	0 (0)
Drowsiness	0 (0)

Table 34 presents the actual statements made by children about side effects.

Table 34: Actual Child Statements about Side Effects of Asthma Control Medications

Category	Actual statement
Thrush	Like I couldn't swallow or nothing
Bad Taste	It tastes nasty

Discussions about Side Effects of Asthma Control Medications Conclusion

Side effects were discussed during 4% (n=12) of clinic visits. In this sample, providers asked the most questions to caregivers and children about whether the child had experienced any side effects from using their asthma control medication. Providers also made the most statements to reassure caregivers and children that the child was not

experiencing a side effect in response to caregivers made a statements or questions about side effects. When caregivers asked questions about side effects, they asked more questions to the provider about whether or not their child was experiencing a side effect. When caregivers made statements to providers, they made the most statements about their children experiencing headaches from their asthma control medication. Children did not ask any questions about side effects but did make statements about the *Bad Taste* of their medication and *Thrush* after using the asthma control medication.

Risks of Asthma Control Medications Discussion Content

This section describes the results of the analysis of the content of communication about asthma control medication risks. Overall, 16% (n=47) of visits included a discussion about risks of asthma control medications.

Provider Questions about Risks of Asthma Control Medications

Under the major category, provider questions about risks, there were two categories that emerged from the analysis of the transcripts of the medical visits: *Steroid causing harm* and *General*.

Table 35 presents the extent to which providers asked questions about risks of asthma control medications. There was one clinic visit in which a provider asked questions about *Steroids causing harm* and the same clinic visit in which the provider asked a question in the *General* category. There was only one provider (n=35) that asked questions about risks during these clinic visits and there was only one question asked in each category.

Table 35: Percentages of Visits of Provider Questions about Risks of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Steroid Causing Harm	0.3% (1)
General	0.3% (1)
Drug-Drug Interaction	0 (0)
Dose	0 (0)
Probability of Risks Occurring	0 (0)
Anabolic Steroid Risks	0 (0)
Bad Taste	0 (0)

Table 36 presents the actual questions made by providers about risks.

Table 36: Actual Provider Questions about Risks of Asthma Control Medications

Category	Actual question
Steroid causing harm	Now you think oh, steroids, steroids are bad right?
General	So what, what risks are associated with this medicine?

Provider Statements about Risks of Asthma Control Medications

Under the major category, provider statements about risks, there were 16 categories that emerged from the analysis of the medical visit transcripts. Providers were most likely to make statements about *General* risks, with statements about *Safety* and *Thrush* being the next highest categories that providers made statements about.

Table 37 presents the extent to which providers made statements about risks of asthma control medications. There were 4% (n=12) of clinic visits in which providers made statements in the *General* category of risks. Providers also made statements in the *Safety* category during 3% (n=8) of clinic visits and providers made statements in the *Thrush* category during 2% (n=6) of clinic visits. The range for provider statements about risks was 0-6. In total, providers made statements about risks during 15% (n=45) of all clinic visits and made a total of 85 statements about risks.

Table 37: Percentage of Visits of Provider Statements about Risks of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Safety	2.7% (8)

Category	Percentage of Visits (N)
Thrush	2.2% (6)
Bad Taste	1.7% (5)
Drowsiness	1.0% (3)
Concerns in Media	0.3% (1)
Anabolic Steroid Risks	1.0% (3)
Hyper-Activity	0.7% (2)
Steroid Causing Harm	1.7% (5)
Reduction in Growth Velocity	1.4% (4)
Reduced Immunity	0.7% (2)
General	4.1% (12)
Dose	1.0% (3)
Feels like Taking Albuterol	0.3% (1)
Long-Term Effects	0.7% (2)
Drug-Drug Interaction	0.3% (1)
Assurance	0.3% (1)
Nosebleeds	0 (0)

Table 38 presents examples of actual statements about risks that providers made during these clinic visits.

Table 38: Actual Provider Statements about Risks of Asthma Control Medications

Category	Actual Provider Statement
Safety	Those have really got a great safety profile
	And being on the daily inhaled medicine is, is quite safe
	It's safer for your body to be on that than taking Albuterol every time you're exercising
Thrush	Because that's a steroid so they can get irritation in the mouth
	Occasionally, people get a little sore throat
	It's important that you rinse your mouth because you don't want to get a yeast infection in your throat
Bad Taste	It doesn't have that powdery taste
	Shouldn't taste bad
	Hey may but it may have a bad taste to it
Drowsiness	The Singulair can be given at any time of day because it doesn't cause sleepiness
Tachyphylaxis	Some kids who use Advair, sometimes they get what's called tachyphylaxis, it kind of works for a while and then causes them not to respond very well
Concerns in Media	I've had....people hear about these things on TV...those concerns come out on TV...every couple of years
	Somebody rehashed it on TV and everytime it happens I have a kid, ah, family call me up and say, we're stopping the medicine because we're scared of it
Anabolic Steroid Side Effects	The steroids don't make you grow hair and muscles, it's just anti-inflammatory
	Well remember...football players are not inhaling steroids, they're taking shots of testosterone, that's very dangerous

Category	Actual Provider Statement
Hyper-activity	I've had a couple, you take it at night before you go to bed. There are a couple of people I've had that have been hyped up on it and to stop it.
	The only side effect as far as that goes, sometimes it hypes them up
Steroids Causing Harm	It's, it's not gonna be harmful
	No, it's not going to hurt him at all
	And there actually were some, with one study showed that increased risk of dying from asthma with people taking Serevent alone
Reduction in Growth Velocity	And the steroid, if you're doing that it's not gonna interfere with growth
	...some children that don't grow quite as fast, but when they hit teenage years, then they just make up for it
Reduced immunity	Because the steroid cause, um, your immune system not to work as well
	It won't make him more susceptible to you know getting infections
General	I'm looking for no side effects from the medicines
	Because all medicines do have some side effects
	And it tends not to have an effect all over the body because we don't want to do that
Dose	No, Advair twice a day is fine, you don't want to do more than twice a day
	But the inhaled ones there's less than 5 percent that gets absorbed into the circulation and already you are starting at such a minimal dose
	Uh huh yep well the Singulair it goes by age so we would go up

Category	Actual Provider Statement
Feel like taking Albuterol	Occasionally, people will feel little bit like they took Albuterol
Long-term effects	I'm not worried about the long term effects of these medicines
	Yeah, oh Advair we don't, I don't worry too much about long term because it's got that low (unclear)
Drug-Drug Interaction	Get back on Claritin and then do the Singulair, you can take them both at the same time and it's no big deal
Assurance	it's [nosebleeds] not from that

Bogardus Dimensions of Risk Communication

Table 39 presents the extent to which providers discussed each dimension in the Bogardus dimensions of risk, with the added dimension of severity of risk. There were 32 instances where there was a specific risk addressed, such as thrush or reduction of growth velocity. There were eight instances of a discussion about probability of a risk occurring, with seven instances of providers using the following words to convey probability: some, not common, a couple, most, rare few, and occasionally. There was only one instance of a provider using a quantitative method in discussing probability, saying: "...I think maybe three people I can think of...that stopped it for some reason."

Table 39: Bogardus Dimensions of Risks Discussed in Medical Visits (n=295)

Bogardus Dimension of Risk Discussed	Frequency (N)
Identity	10.8% (32)
Permanence	0.7% (2)
Timing	0.7% (2)
Probability	2.7% (8)
Qualitative Discussion of Risk	2.4% (7)

Bogardus Dimension of Risk Discussed	Frequency (N)
Quantitative Discussion of Risk	0.3% (1)
Values	0.3% (1)
Severity	0.3% (1)

Caregiver Questions about Risks of Asthma Control Medication

Under the major category, caregiver questions about risks, there were five categories that emerged from analysis of the transcripts: *Steroid Causing Harm, Drug-Drug Interaction, Dose, Probability of Risks Occurring, and General*. Caregivers were most likely to ask if the steroids caused harm to the child.

Table 40 presents the extent to which caregivers asked questions about the risks of asthma control medications. Caregivers asked about steroids causing harm in 1% (n=3) of all clinic visits. Caregivers asked about drug-drug interactions during 0.3% of clinic visits (n=1). Caregivers asked about the strength of the dose being too high during 1% (n=2) of clinic visits and also asked about risks during 1% (n=2) of clinic visits. The range for caregiver questions about risks was 0-2. In total, caregivers asked questions in 4% (n=11) of clinic visits and asked a total of 12 questions.

Table 40: Percentage of Visits of Caregiver Questions about Risks of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Steroid Causing Harm	1.7% (5)
General	0.7% (2)
Drug-Drug Interaction	0.3% (1)
Dose	0.7% (2)
Probability of Risks Occurring	0.3% (1)
Anabolic Steroid Risks	0 (0)
Bad Taste	0 (0)

Table 41 presents the actual questions caregivers asked during these clinic visits.

Table 41: Actual Caregiver Questions about Risks of Asthma Control Medications

Category	Actual Question from Caregiver
Steroid Causing Harm	There is not any kind of danger in that Advair is they?
	Ok, but I remember you telling me once before that could be dangerous doing this/
	And it's not tough on the liver?
Drug-Drug Interaction	And it's safe together? (Singulair and antihistamine)
Dose	Ok, that's not too much?
	And it wouldn't hurt him?
	And the dose he is taking is still ok?
Probability of Risks Occurring	So it's not common
General	Ok, so what are the side effects from the Singulair?
General	That medicine he's taking, does it do anything to his (unclear)?
	So the medicine don't have nothing to do with that?

Caregiver Statements about Risks of Asthma Control Medications

Under the major category, caregiver statements about risks, there were six categories that emerged from the transcript analysis: *General Nosebleeds*, *Long-Term Effects*, *Bad Taste*, *Thrush*, and *Concerns in Media*. Caregivers were most likely to ask questions in the *General* category.

Table 42 presents the extent to which caregivers made statements about risks of asthma control medications during these clinic visits. Caregivers made statements in the *General* category during 1% (n=3) of all clinic visits. Caregivers made one statement (0.3% of all clinic visits) each in these categories: *Nosebleeds*, *Long-Term Effects*, *Bad Taste*, *Thrush*, and *Concerns in Media*. The range for caregiver statements about risks was 0-2. In total,

caregivers made at least one statement during 3% (n=8) of all clinic visits and made a total of ten statements.

Table 42: Types and Frequencies of Caregiver Statements about Risks of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Safety	0 (0)
Thrush	0.3% (1)
Bad Taste	0.3% (1)
Drowsiness	0 (0)
Concerns in Media	0.3% (1)
Anabolic Steroid Risks	0 (0)
Hyper-Activity	0 (0)
Steroid Causing Harm	0 (0)
Reduction in Growth Velocity	0 (0)
Reduced Immunity	0 (0)
General	1.0% (3)
Dose	0 (0)
Feels like Taking Albuterol	0 (0)
Long-Term Effects	0.3% (1)
Drug-Drug Interaction	0 (0)
Assurance	0 (0)
Nosebleeds	0.3% (1)

Table 43 presents the actual statements made by caregivers about the risks of asthma control medications during these visits.

Table 43: Actual Caregiver Statements about Risks of Asthma Control Medications

Category	Actual Statements
General	(unclear) research on it I did not want him, I didn't feel like his symptoms were strong enough to risk the side effects of that
	But I'm just worried about all these steroids that we keep pumping into him
	Yeah I give it to him when, when I see that it is getting to that point but I don't want to give it to him every night just because it's a steroid but I do give it to him and it relieves his...
Nosebleeds	But still he gets nosebleeds
	Well he gets nosebleeds
Long-Term Effects	Yeah, because I worry about the long term
Bad Taste	Yeah, it will taste better
Thrush	I was really concerned he was gonna get the yeast in his mouth and all this stuff
Concerns in Media	I heard on the TV you know they say all kinds of things on it

Children's Questions about Risks of Asthma Control Medications

Under the major category, child questions about risks, there were three different categories that emerged after analysis of the transcripts. The categories were: *Anabolic Steroid Side Effects*, *Steroid Causing Harm*, and *Bad Taste*. Each type of question occurred in one visit (**Table 44**).

Table 44 presents the extent to which children asked questions about risks of asthma control medications. Children asked one question in each of the three categories, totaling three questions during the clinic visits.

Table 44: Types and Frequencies of Child Questions about Risks of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Steroid Causing Harm	0.3% (1)
General	0 (0)
Drug-Drug Interaction	0 (0)
Dose	0 (0)
Probability of Risks Occurring	0.3% (1)
Anabolic Steroid Risks	0.3% (1)
Bad Taste	0.3% (1)

Table 45 presents the actual questions made by children about the risks of their asthma control medications during the audiotaped medical visits.

Table 45: Actual Child Questions about Risks of Asthma Control Medications

Category	Actual Questions
Anabolic Steroid Side Effects	Wait, does steroids um, cut off my fat or something?
Medication Causing Harm	It won't hurt me will it?
Bad Taste	Is it going to taste better?

Children's Statements about Risks of Asthma Control Medications

Children did not make any statements about risks during these clinic visits.

Discussions about Risks of Asthma Control Medications Conclusion

Risks were discussed during 16% (n=47) of all clinic visits. There was one provider that asked questions about risks and there were two instances of providers asking about risks to children and caregivers. Providers were most likely to make statements about *General* risks and statements about the safety of the asthma control medication. Caregivers were most likely to ask questions about the control medication causing harm to his/her child and were most likely to make *General* statements about risks, much like providers.

Children asked questions that compared anabolic steroid side effects to inhaled corticosteroid side effects, the medication causing them harm and the *Bad Taste* of the medication.

Benefits of Asthma Control Medications Discussion Content

This section describes the results of the analysis of asthma control benefit discussions in the 47% (n=140) of medical visits where benefits were discussed.

Provider Questions about Benefits of Asthma Control Medications

Under the major category, questions about benefits of asthma control medications, questions from providers fell into one of eight categories. Providers were most likely to ask questions about symptom control and prevention (N=25).

Table 46 presents the extent to which providers asked questions about benefits of asthma control medications. As stated earlier, providers were most likely to ask questions about symptom control and prevention (n=25), asking a total of 33 questions about it. The range for provider questions about benefits was 0-8. In total, providers asked questions about the benefits of asthma control medications during 32 clinic visits and made a total of 49 statements.

Table 46: Percentage of Visits of Provider Questions about Benefits of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Symptom Control/Prevention	8.5% (25)
Ease of Use	0.3% (1)
Quality of Life	0.3% (1)
Adherence	0.7% (2)
Re-iteration	0.3% (1)
Teach-Back	1.0% (3)
General	0 (0)
Potency	1.4% (4)

Table 47 presents the actual questions made by providers during these clinic visits.

Table 47: Actual Provider Questions about Benefits of Asthma Control Medications

Category	Actual Questions
Symptom Control/Prevention	Good, can you tell a difference?
	So it has improved?
	Did it seem to help when we did take something everyday
Ease of Use	How long is it going to take him to do the Pulmicort in the inhaler?
Quality of Life	Are you worried she is going to get sick and have to come in?
Adherence	When he takes his Asmanex, does he stay clear most of the time?
Re-iteration	It works good?
Teach-Back	And hopefully doing this, what are we going to watch for?
	Now I've got a question for you, what does that mean?
	To keep it away so you don't have to use your?
Potency	You started two weeks ago, and it's such a strong medicine that you're already better right?
	Okay, and that's even using your Advair, it doesn't help with that?

Provider Statements about Benefits of Asthma Control Medications

Under the major category, provider statements about benefits, statements fell into one of 20 categories. Providers were most likely to make statements about symptom control and prevention (n=66) as well as general benefits (n=44).

Table 48 presents the extent to which providers made statements about asthma control medication benefits. Providers also made frequent statements about the benefits of control medication adherence (n=22), as well as quality of life (n=19), and a time-table

for when caregivers and children could expect to realize benefits (n=19). The range for provider statements about benefits of asthma control medications was 0-9. Providers made a total of 338 statements about the benefits of asthma control medications during 128 medical visits.

Table 48: Percentage of Visits of Provider Statements about Benefits of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Adherence	7.4% (22)
Potency	7.1% (21)
General	14.9% (44)
Teach-Back	0 (0)
Multiple Indications	4.7% (14)
Decreases Inflammation in Lungs	3.0% (9)
Consequences of Not Treating	0.7% (2)
Symptom Control/Prevention	22.3% (66)
Quality of Life	6.8% (20)
Pulmonary Function	0.3% (1)
Reduced Need for Rescue Medication	5.4% (16)
Acute Symptoms/Prior to Exercise	3.0% (9)
Length of Time Medication Works	0.7% (2)
Goals of Treatment	1.7% (5)
Improvement Time-Table	6.4% (19)
Ease of Use	3.0% (9)
Dose	0.3% (1)
Prevention of Bad Asthma Outcomes	1.0% (3)
Inhalation Technique	0.7% (2)
Anticipating Benefit	0.3% (1)
Bronchitis	0 (0)

Table 49 presents examples of the actual statements that providers made about the benefits of asthma control medications.

Table 49: Actual Provider Statements about Benefits of Asthma Control Medications

Category	Actual Statement
Adherence	You do it in the morning and at night and it will make a big difference
	So think of it like birth control, you want to do it everyday, if it is going to work you gotta do it everyday
	But you've got to take it everyday for it to work
Potency	The Flovent is dynamite
	Advair is the strongest thing for asthma
	It's not like using the Albuterol inhaler when you use it and in a few minutes you can tell a difference but it is much more powerful
Multiple Indications	Singular is a medicine that can be used for both allergies and asthma
	Singular helps with asthma and helps allergies and can be used in addition to the Zyrtec that he is already on
	Singular is an allergy medicine and I chose it because it also helps with asthma
Decreases Inflammation in Lungs	Advair you know when she's another inhaler which decreases the inflammation in your lungs
	So it can be used long-term but it is only acting locally to get rid of the inflammation with her asthma
	Then it helps to kind of control some of the inflammation, some of the irritation of the lungs
General	Advair is good
	See, we're having less and less spells which is good
	It just has the steroid in it but it's a good one, it's one puff twice a day

Category	Actual Statement
Consequences of Not Treating	Children who have untreated you know especially if there's evidence of asthma in the lung function that we do okay then um, then those children just don't feel healthy
	They have long issue problems even in long, later on in life you know like COPD or emphysema even without smoking ever in their life you know so there is consequences to not treating
	Like she say, you know they don't concentrate as well
Symptom Control/Prevention	The goal is to use the preventatives, the Advair, alright and completely control your symptoms so that you don't need to use the Albuterol
	The Pulmicort is there to prevent the symptoms
	Used to control and prevent, your word, you said prevention earlier, would prevent his coughing, wheezing, with trouble with play, exercise, recess, sneeze, mucus, trouble with sleep, ok that's the Pulmicort
Quality of Life	I want her not to cough and she needs to run and be able to play
	Oh, you better believe it, I want you to run like the wind
	I mean that worry, I mean we get rid of that worry that would be great
Lung Function	Ok, so that this is (unclear) asthma and improve lung function

Category	Actual Statement
Reduced Need for Rescue Medication	He should be on enough maintenance medicine you know occasionally, once in a while, yeah he is going to need Albuterol but we hope not everyday
	That's our goal is to get him to the point where he doesn't need the Albuterol everyday
	Yeah I think the Advair is gonna prevent him from needing the Albuterol at least I hope
Acute Symptoms/Prior to Exercise	Now the steroid is not helpful for acute episodes when he is wheezing ok
	Now this one will not help you when you are wheezing
	That is what Advair is, it wouldn't make a difference right away within period of 30 minutes prior to exercise
Length of Time Medication Works	Advair, the purple disk, when you brush your teeth in the morning, it does have a long-acting steroid in it and a long-acting Albuterol so the benefit is it hangs out in the lungs over a 12 hour period
	But then it also has a long-acting Albuterol in it that helps kind of open the airways and works for about 10-12 hours
Goals of Treatment	Okay but our goal is not to need it, no cough at night, no cough with exercise, no shortness of breath with exercise, no missed school, and no side effects from the medicine
	And that's one of the ways how we judge if it is working for you, whether you are needing your Albuterol, are you able to sleep through the night without coughing, are you able to exercise, you know run around, play without coughing
	Our goal is to make it so she will be able to run and play and laugh and be excited and not have trouble breathing

Category	Actual Statement
Improvement Time-Table	So the fact is we still don't have perfect, it's still going to take two more weeks before we have perfect control with that Asmanex
	And it takes a while to see some effect
	And the Advair helps get things back to normal because you're, you know you're not wheezing right now but your lungs are still damaged and the Advair helps repair that but it takes time
Ease of Use	And if you can do it, it's a lot easier than the Pulmicort you're taking, it's faster and it's easier
	Singular is easy because you take it once a day and it will help that nose too
	A lot easier to use than having to use the Flovent
Dose	Well the interesting thing about Advair (unclear) is there is a dose at which you don't get much of a response after you get there
	And interestingly with the medicine that's in Advair, uh, the one that they change the dosing on the 100, the 250, the 500, that medicine itself, once you get to just a little bit over 100, you get very little improvement with
Prevention of Bad Asthma Outcomes	The medicines that are in Advair have been shown to keep kids out of the hospital, prevent death from asthma, prevent hospital admissions from asthma, prevent asthma attacks so you have to take your good with the bad
	That medicine has saved a lot of people from being sick and having to go to the emergency room and all that sort of stuff

Category	Actual Statements
Prevention of Bad Asthma Outcomes	...The Flovent more than Singulair has been actually improve pulmonary function testing and prevent these chronic asthma exacerbations, prevent people from getting bad enough to go into the hospital or go to the emergency room
Technique	Yeah, it won't work if you don't do it right so you've got to do it the right way
	Here's the other thing with your Advair, you've got to use it the right way. If you don't do it the right way it won't work well
	If you don't...you go (quick breath) the medicine stops right here, never gets to your lungs and it won't work. For the medicine to work it has to get where you want it
Anticipating Benefit	and I'd love to hear that

Caregiver Questions about Benefits of Asthma Control Medications

Under the major category, questions about benefits, caregiver questions fell into one of three categories. The categories were: *Symptom Control/Prevention*, *Quality of Life*, and *General*. Caregivers were almost equally likely to ask questions about all three categories, as discussed below.

Table 50 presents the extent to which caregivers asked questions about benefits of asthma control medications. Caregivers asked questions about symptom control/prevention (n=1), quality of life (n=2), and general questions about benefits (n=2). The range for caregiver questions about benefits of asthma control medications was 0-1. In total, caregivers asked five questions about benefits during five medical visits.

Table 50: Percentage of Visits of Caregiver Questions about Benefits of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Symptom Control/Prevention	0.3% (1)
Ease of Use	0 (0)
Quality of Life	0.7% (2)
Adherence	0 (0)
Re-iteration	0 (0)
General	0.7% (2)
Teach-Back	0 (0)
Potency	0 (0)

Table 51 presents all of the actual questions caregivers asked providers about benefits during these medical visits.

Table 51: Actual Caregiver Questions about Benefits of Asthma Control Medications

Category	Actual Questions from Caregivers
Symptom Control/Prevention	Ok, it just helps control what triggers?
Quality of Life	Would you expect that with his Advair using it twice a day the way you had recommended that at some point he would be able to run as hard as he wanted to?
	Should that help her too with like exercising and, and stuff like that?
General	No, you know what's made the difference in my opinion?
	He seems to be doing a lot better with the Singulair than without, you know?

Caregiver Statements about Benefits of Asthma Control Medications

Table 52 presents the extent to which caregivers made statements about the benefits of asthma control medications for their children. Caregivers were most likely to make statements about general benefits of asthma control medications (n=24) during these visits. Caregivers made two statements in each of the following categories: *Symptom Control/Prevention* and *Anticipating Benefit*. Caregivers made one statement in each about of the following categories: *Quality of Life*, *Ease of Use*, and *Bronchitis*.

Caregivers made six statements in each of the following categories: *Potency* and *Medication Adherence*. The range for caregiver statements about benefits of asthma control medications was 0-7. In total, caregivers made 50 statements about the benefits of asthma control medications during 36 medical visits.

Table 52: Percentage of Visits of Caregiver Statements about Benefits of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Adherence	2.0% (6)
Potency	2.0% (6)
General	8.1% (24)
Teach-Back	0 (0)
Multiple Indications	1.0% (3)
Decreases Inflammation in Lungs	0 (0)
Consequences of Not Treating	0 (0)
Symptom Control/Prevention	0.7% (2)
Quality of Life	0.3% (1)

Category	Percentage of Visits (N)
Pulmonary Function	0 (0)
Reduced Need for Rescue Medication	0 (0)
Acute Symptoms/Prior to Exercise	0 (0)
Length of Time Medication Works	0 (0)
Goals of Treatment	0 (0)
Improvement Time-Table	0 (0)
Ease of Use	0.3% (1)
Dose	0 (0)
Prevention of Bad Asthma Outcomes	0 (0)
Inhalation Technique	0 (0)
Anticipating Benefit	0.7% (2)
Bronchitis	0.3% (1)

Table 53 presents examples of the actual statements made by caregivers about the benefits of asthma control medications.

Table 53: Actual Caregiver Statements about Benefits of Asthma Control Medications

Category	Actual Statement from Caregivers
Symptom Control/Prevention	Um hmm...it keeps it under control
	Preventative
Anticipating Benefit	I hope it does
	It seems like a really good direction to go in because...when the steroids were in her...she had really good health
	I would love not to hear that cough
Potency	Well...I'm just a little worried that they didn't see...any improvement is what I'm trying to say
	Most of the time-well she seems to keep a cough a lot
	Because they put me on it because I have had asthma for years, and Advair don't help me, now I know everybody is different, but for me watching her and hearing her you know and everyday to me and I don't think it's doing any good
Adherence	She didn't think she needed it anymore because she wasn't coughing or having trouble breathing, I said, that's why you're not coughing
	When she, as long as she takes her medicine
	The reason with the Advair, she told him if he would use it everyday he that he might could come off the Singulair too
Child-Related Quality of Life	It won't be like he is worn out and they pull him out after a while
Ease of Use	Not long
Bronchitis	Well, he hasn't had anything to do with bronchitis since May of last year
Multiple Indications	Uh huh I think it is helped a lot because last year with his eye swelling
	They take it at night, it just helps keep those allergies under control
	To help your sinuses and all that in your head
General	I think upping the Singulair helped too
	It's better, it's getting better
	Yes, he is doing pretty good with that

Children's Questions about Benefits of Asthma Control Medications

This section will describe the extent of children's participation in discussions about control medication benefits as well as describe the actual content of both questions and statements from the content analysis of the transcript data.

Children's questions fell into one of two categories: quality of life and general questions about benefits. Children asked only two questions during the audiotaped medical visits.

Table 54 presents the extent to which children asked questions about asthma control medications during these visits.

Table 54: Percentage of Visits of Child Questions about Benefits of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Symptom Control/Prevention	0 (0)
Ease of Use	0 (0)
Quality of Life	0.3% (1)
Adherence	0 (0)
Re-iteration	0 (0)
General	0.3% (1)
Teach-Back	0 (0)
Potency	0 (0)

Table 55 presents both of the questions children asked during these medical visits.

Table 55: Actual Child Questions about Benefits of Asthma Control Medications

Category	Actual Questions
Quality of Life	Just not that hard right? [Running]
General	Can I (unclear) if I take the medicine?

Children's Statements about Benefits of Asthma Control Medications

This section will describe the extent of children's statements about benefits of asthma control medications. Children's statements fell into five categories: *Reduced Need for Rescue Medication*, *Potency*, *Symptom Control/Prevention*, *Adherence*, and *General*.

Children made the most statements about general benefits of asthma control medications (n=6) as well as benefits of medication adherence (n=3). **Table 56** presents the extent to which children made statements about the benefits of asthma control medication adherence. The range for child statements about benefits was 0-2. Children made a total of 15 statements about benefits during 10 medical visits.

Table 56: Types and Frequencies of Child Statements about Benefits of Asthma Control Medications (N=295)

Category	Percentage of Visits (N)
Adherence	1.0% (3)
Potency	0.3% (1)
Teach-Back	1.7% (5)
General	0.3% (1)
Multiple Indications	0 (0)
Decreases Inflammation in Lungs	0 (0)
Consequences of Not Treating	0 (0)
Symptom Control/Prevention	0.3% (1)
Quality of Life	0 (0)

Category	Percentage of Visits (N)
Pulmonary Function	0 (0)
Reduced Need for Rescue Medication	0.7% (2)
Acute Symptoms/Prior to Exercise	0 (0)
Length of Time Medication Works	0 (0)
Goals of Treatment	0 (0)
Improvement Time-Table	0 (0)
Ease of Use	0.3% (1)
Dose	0 (0)
Prevention of Bad Asthma Outcomes	0 (0)
Inhalation Technique	0 (0)
Anticipating Benefit	0 (0)
Bronchitis	0 (0)

Table 57 presents the actual statements made by children about the benefits of asthma control medications.

Table 57: Actual Child Statements about Benefits of Asthma Control Medications

Category	Actual Statements
Reduced Need for Rescue Medication	It helps me not to use it as much
	Nah, I probably wouldn't need it
Potency	Umm, it helps a little bit but not much
Symptom Control/Prevention	Under control, yeah
Adherence	Take it
	Yeah, usually when I take it, I wait a couple minutes and then I have no more asthma for the rest of the day
	Medicine that you take everyday and night for 10 seconds
Teach-Back	To make it feel better
	To keep it situated
General	That's why I haven't had as much problems probably since I started taking the Singulair

Discussions about Benefits of Asthma Control Medications Conclusion

Asthma control medication benefits were discussed during 47% (n=140) of all medical visits in this sample. Providers were most likely to ask questions about whether or not the asthma control medication was controlling and preventing asthma symptoms.

Providers also attempted to engage children in these visits by directly asking questions to the child about the purpose of the asthma control medication, such as asking about benefits of asthma control medications, as well as medication adherence. In total, providers asked a total of 48 questions about the benefits of asthma control medications. Providers also made the majority of the statements, making a total of 338 statements about the benefits of asthma control medications. Providers were most likely to make statements about symptom control and prevention (n=66) and general statements about medication benefits (n=44). Providers also had the largest breadth of statements, talking about a total of 20 different categories.

Caregivers asked five questions about the benefits of asthma control medications in three different categories. Caregivers made a total of 50 statements about benefits of asthma control medications in nine different categories. Caregivers were most likely to make statements about general benefits of asthma control medications (n=24), while also discussing the medication's lack of effectiveness in addition to the benefits of the child adhering to the medication regimen.

Children asked a total of two questions about the benefits of asthma control medications in one of two different categories. Children asked questions about quality of life and general benefits of asthma control medications. Children made a total of 15 statements

about asthma control medications, making the most statements about general benefits of asthma control medications and the benefits of medication adherence. Children also made statements about the reduced need for taking a rescue medication because of the control medication, the lack of effectiveness of the asthma control medication, and symptom control and prevention.

Conclusion about Content Analysis of Side Effect, Risk, and Benefit Discussions

Providers spoke the most in all three major categories: side effect discussions, risk discussions, and benefit discussions. Children spoke the least in all three major categories as well. Providers had a 1.4:1 ratio of their statements about side effects to the caregiver statements about side effects and had a 4.67:1 ratio of their statements about side effects to the child's statements about side effects. These ratios increased during discussions about risks. Providers had an 8.5:1 ratio of their statements about risks to the caregiver statements about risks, while children did not make any statements about risks of asthma control medications. Finally, providers had a 6.76:1 ratio of their statements about benefits of asthma control medications to caregiver statements about benefits of asthma control medications and had a 22.53:1 ratio of their statements to every child statement about benefits. The most-discussed side effect was headaches from Singulair and the most-discussed specific risk was thrush. The most-discussed specific benefit of asthma control medications was asthma symptom control and asthma symptom prevention.

The next chapter will present the discussion and conclusion to this dissertation study.

CHAPTER SIX: DISCUSSION

The purpose of this dissertation was to better understand communication about asthma control medications side effects, risks, and benefits. This study helps address gaps in the literature regarding patient-provider communication between medical providers, children, and their caregivers about adverse effects and benefits. While the shared decision making literature has stressed the importance of risk-benefit communication, this was one of the first studies to examine the content and predictors of actual discussions about side effects, risks, and benefits among providers who treat children (Makoul 2002). Both qualitative and quantitative methods were used to examine the communication about asthma control medication side effects, risks, and benefits, as well as the impact that communication has on asthma control medication adherence and caregiver and child-reported concerns about side effects. The following sections summarize the findings and discuss the implications of the qualitative and quantitative results, the major limitations and strengths of the study, and present potential directions for future research.

Summary of Findings

Discussions of Side Effects of Asthma Control Medication

Audiotape analysis results revealed that only four percent (n=12) of medical visits contained discussions about side effects of asthma control medications. Providers rarely asked questions about side effects of asthma control medications, specifically asking

children and caregivers whether they were experiencing any problems with the medication; providers only asked questions about side effects, however, during *five* total visits. According to clinical practice guidelines of the National Asthma Education and Prevention Program of NHLBI, it is important for providers to discuss side effects with patients (NAEPP 2007) at *every* visit.

The national clinical practice guidelines instruct providers to closely monitor side effects of asthma control medications, asking patients at every visit whether they experienced any side effects of the asthma control medication. Yet, providers rarely ask questions as simple as: “Have you had any problems with your asthma control medication?”

Providers need to ask children and their caregivers if they have any problems or concerns about side effects of asthma control medications in order for providers to alleviate concerns and discuss changing therapy to a more suitable control medication. This could help reduce children or caregivers from under-using or discontinuing asthma control medications on their own. Improved adherence to asthma control medications may result in fewer school days missed by children, reduced healthcare costs, and better asthma control (Williams et. al. 2004 and Bender and Bender, 2005).

Provider demographics did not show an association with side effect communication.

There were, however, certain child characteristics that were associated with a discussion about side effects. Specifically, children who were younger were more likely to have a visit that included a discussion about side effects. Future research could help determine why this finding occurred, but it could be that providers discuss side effects with younger

children and may not discuss side effects with those same children as the child ages. It should be noted, however, that providers rarely discussed side effects during these visits. Providers should make sure to engage children of all ages in conversations about the side effects of their asthma control medications. If children and caregivers know what to expect from their medications, then they may be able to prevent and treat side effects. Additionally, providers need to ask the child to verbalize their thoughts and feelings about their concerns about medication side effects (NAEPP, 2007). This could improve control medication adherence and decrease levels of concerns about side effects.

Previous studies in adult patients have shown that adults do not always discuss medication-related symptoms with their providers (Gandhi et. al. 2003, Weingart et. al. 2005, Wilson et. al. 2007). Our results of side effect discussions also show that caregivers and children rarely discuss medication side effects with their providers. Many side effects are preventable and treatable and providers should make sure to discuss side effects with all children and their caregivers. One of the reasons adult patients do not ask their providers questions during their medical visit is because they are reluctant to ask their providers questions (Sleath et. al. 1999). Sleath and colleagues (1999) also found that physicians perceive patient question-asking positively, rating those who asked questions as more interested and more assertive than patients who do not ask questions (Sleath et al. 1999). Thus, providers should try to encourage children and caregivers to ask questions about side effects during every visit.

When providers did discuss side effects with children and their caregivers, they were most likely to ask general questions about side effects (i.e. “She didn’t have no bad reaction to it or anything like that?”) and make Assurance statements to children and caregivers. Assurance statements were categorized as statements to attempt to put caregivers at ease and assure them that the symptom the caregiver thought was medication-related was not. When caregivers make a statement or ask a question about a symptom they think is medication-related, providers should encourage a discussion about side effects and not cut caregivers off while the caregiver is speaking.

As stated previously, discussions about side effects were found in only four percent of medical visits. Prior studies of provider-patient communication have found that discussions about side effects were rare (Sleath et. al. 2007, Sleath et. al. 1999), while other studies have found that discussions about side effects were very common (Young et. al. 2006). The reason for such a high frequency in the Young et. al. (2006) study could be because that study examined new prescriptions for antidepressants in white, middle-aged women and those women were standardized patients. The Young et. al. (2006) study may not be generalizable to this dissertation study because that study used standardized patients. Also, the Young and colleagues (2006) study covertly audiotaped medical visit interactions (with prior provider consent), whereas in our study, the providers knew they were being audiotaped and no attempt was made to hide the audio recorder. The Young and colleagues (2006) study was also conducted in large metropolitan areas in the United States, whereas our study was conducted in rural areas in North Carolina. Finally, the Young et. al. (2006) study was a smaller component of a

randomized experiment, while in our study, there was no randomization process and providers delivered usual care to children.

There were also no differences in characteristics of caregivers or asthma control medications that were associated with discussions of side effects. The finding is interesting because of the general concern among the public about the safety and long-term effects of inhaled corticosteroids. Despite this, the finding that characteristics of the medication was not a significant contributor to discussions about side effects could have been partially due to the extremely low frequency of the discussions about side effects.

It is also worth noting that side effects may still affect children whose visits did not include a discussion of side effects. This study measured communication about medication side effects and not child or caregiver perception of side effects at the office visit. It is possible that a portion of the patients not discussing side effects experienced at least one side effect of the medications, for example bad taste or thrush. In fact, our study showed that 83 children reported at least a little concern or problem with side effects one month after the visit with their provider. While this study did not examine specific side effects that caused children the most problems or concerns, prior research has found that remarkably few children use their metered dose inhaler, diskus, and dry powder inhaler devices correctly, which could result in the patient experiencing side effects, such as unpleasant taste of the medication or oral thrush (Sleath et. al. 2011).

Providers could ask the following question to both children and caregivers to assess whether or not the child has experienced any side effects from the medication (NAEEP, 2007): “Has your asthma medicine caused you any problems?”. This simple, open-ended question can be used to gauge if the child has experienced any problems with the medication; in this case, side effects. By directly asking the child about the problems in taking the medication, the provider is engaging the child and involving them in their own health care. This begins to build autonomy in medication taking in children and initiates their understanding of causal relationships. Similarly, when speaking with adolescents, providers can speak to teenagers akin to how they would speak with an adult (Sleath et. al., 2003).

There were instances of communication that was not fully interactional. For example, there were instances in which the caregiver was speaking to the provider about the side effects of asthma control medications, such as headaches, and the provider cut the caregiver off mid-sentence to tell them: “Not related to her asthma medicine”. The provider not discussing the problematic headaches the child was experiencing may lead to the caregiver and child reducing or eliminating doses in order to avoid the headaches. In fact, statements from caregivers during these visits did confirm that caregivers stopped their child from taking an asthma control medication based on the side effects that were experienced without first consulting the child’s provider. This type of intentional non-adherence to asthma control medications from caregivers of asthmatic children points to an increased need for providers to discuss the side effects of asthma control medications with caregivers and children. This discussion may prevent caregivers from having their

child discontinue their asthma control medication because of concerns about side effects of the medication. The national asthma practice guidelines state that most non-adherence to medications results from concerns about the medications that the patient and/or caregivers have not talked about with their provider (NAEPP, 2007). Providers can discuss concerns about medications in a way that both children and caregivers understand, thus catching potential non-adherence earlier. Non-adherence to asthma control medications may result in sub-optimal asthma control and lead to increased healthcare costs and asthma symptoms (Williams et. al. 2004 and Bender and Bender, 2005).

Children did not ask any questions about side effects during these visits. Children should be taught about their medications and providers should encourage children to ask questions about their medications (Bush et. al. 1999 and Bush and Sleath, 2003). Adolescents as young as 13 years old want to know about the side effects of their asthma medications and what to do about them if they experience them (Raynor et. al. 2004).

Although children did not ask questions about side effects, children did make statements regarding side effects of their asthma control medications, but it was always anecdotal information after the caregiver spoke to the provider. This study's results found that discussions about side effects were more prevalent in younger children than older children. These findings together confirm prior research observing that caregivers usually speak for their children (Tates and Meeuwesen, 2000, Wissow et. al. 1998). Prior studies have found that child involvement decreases the amount of time that caregivers

speak to the medical provider (Tates and Meeuwesen, 2000). Providers and caregivers both, intentionally or not, suppress the child's discussions during the medical visit.

Children need to speak to their medical providers in order for providers to understand exactly how the child feels about using a medication, especially because children as young as nine years old use their asthma medications on their own (Orrel-Valente et. al. 2008). Younger children's visits were more likely to include a discussion about side effects, but providers need to discuss side effects with older children as well, which the national asthma guidelines encourage (NHLBI, 2007).

Children as young as seven years old can begin to learn causal relationships about their health (i.e. taking Singulair may result in a headache) (Sleath et. al. 2003). Providers and caregivers should encourage children to participate in medical discussions by asking questions and discussing their experiences using an asthma control medication. Future research should examine interventions that encourage children to participate in discussions about side effects and whether that communication impacts children's concerns about using asthma control medications.

Side effects were discussed during twelve distinct visits. According to the national asthma practice guidelines (NAEPP 2007), providers should have discussed side effects as well as child and caregiver concerns about side effects during all visits. Therefore, providers need to dramatically increase their performance of this behavior in order to achieve consistency with the guidelines. Even when providers discuss medication risks with new prescriptions, an ongoing discussion about side effects should still occur at

every visit to monitor the medication's efficacy and address any concerns in order to maximize the child's use of the medication. It is important to note that in order for discussions about side effects to have occurred, the child had to previously experience a side effect; they could not simply just discuss side effects. This is a limitation of the study.

Discussions about Risks of Asthma Control Medications

Risks were discussed in less than one-fifth of these visits. In both of the instances where the provider asked about risks of asthma control medications, the provider used those questions to start the discussion about risks. While it may be counter-intuitive that providers would ask questions to caregivers and children about risks of asthma control medications, it is important for providers to assess understanding of the discussion after the risks were discussed.

Previous studies have found that 40-80% of medical information discussed in medical visits is forgotten immediately and half of the information that is retained is incorrect (Kessels 2003). The Teach-Back Method is a method that confirms the information the provider discussed during the visit is retained by the caregiver and child (DeWalt et. al. 2010). The Teach-Back method calls for providers to ask caregivers and children about the information presented during the visit to test how well the provider explained each concept. Asking the child and caregiver to repeat the concepts that were discussed in the communication about risks could be a very strong tool that aids the provider in discussing a sensitive topic, such as the risk of adverse effects from asthma control medications.

Since retaining information is a key aspect in how caregivers and children perceive the safety of a medication, it is important for providers to ask questions about the risks that were discussed to ensure that both caregivers and children correctly understand the risks involved in using an asthma control medication. The providers in these visits did not use the Teach-Back method when discussing the side effects and risks of asthma control medications. Future research should investigate an intervention about the effect of using the Teach-Back Method and caregiver and child comprehension of asthma control medication side effects and risks.

When providers made statements about the risks of asthma control medications, they were most likely to make General statements about risks, meaning that the provider did not identify a specific risk in using the medication. Medical providers are experts on the treatment of diseases, such as asthma, and should discuss the salient aspects of pharmaceutical therapy, such as risks. Using the phrase that was used in these medical visits, “And it tends not to have an effect all over the body because we don’t want to do that,” the provider does not tell the caregiver or child risks that (s)he should be concerned about. By not discussing specific risks of using these medications, caregivers and children may be more susceptible to decreased adherence if they experience one of these risks, such as thrush. It may be possible that providers discussed specific risks during previous visits. However, national practice guidelines (NAEPP 2007) state that providers should address children’s and caregivers’ concerns at every visit, which may include a discussion about medication risks.

Likewise, when providers make a statement such as a *Safety* statement, saying, “And being on the daily inhaled medicine is, is quite safe,” providers are not really discussing a specific risk with children and their caregivers. Saying that the medication is safe is not discussing risks, but the *absence* of risks. This may lead to caregivers or children thinking that the medication will not cause any adverse effects, which is not a realistic perception of pharmacotherapy. When providers did discuss specific risks, they were more likely to discuss *Thrush* and *Bad Taste*.

When caregivers spoke about risks, they were most likely to ask questions about the asthma control medication causing harm to the child. An example of this kind of question in these visits was: “There is not any kind of danger in that Advair is they (sic)?” Caregivers also made the most statements about *General* risks. An example of this kind of statement was: “Yeah I give it to him when, when I see that it is getting to that point but I don’t want to give it to him every night just because it’s a steroid but I do give it to him and it relieves his...” In this example, the caregiver did not even fully speak the entire sentence before the provider cut the caregiver off. The provider tells the caregiver to give the medication to the child every night during the allergy season after (s)he cut off the caregiver. The provider misses a key opportunity to discuss the importance of adherence to asthma control medications and the resulting improved control as a result of using the medication.

Confirming the results of the side effect discussions, children only spoke about risks during three medical visits. It is important to note that while only three children spoke

any about the risks of asthma control medications, almost one-third of children reported a problem or concern about side effects one month after the medical visit. This suggests that children do have concerns about side effects of their asthma control medications, but the vast majority of children are not discussing this with their medical provider. As discussed earlier, children should be taught to discuss any concerns about risks or side effects with their provider, because this discussion may lead to providers preventing or treating risks before they become side effects. However, before any discussion about risks can take place, providers need to explain to children specific risks that are involved in using asthma medications and if the risk is preventable (i.e. thrush), then how to avoid those risks. Providers can then ask children directly if they are they think they are experiencing any side effects and also if they have any concerns about the potential side effects, which would fulfill the Bogardus dimension of discussion about the patient's values regarding the risks (Bogardus 1999).

Children should be taught how to effectively communicate during medical encounters. Both caregivers and medical providers should encourage children to be involved in the discussions, since children as young as nine years old use their asthma control medications without parental supervision (Eggleston et. al. 1998, Orrell-Valente et. al. 2008). Finding that children rarely participate in discussions during medical visits is not surprising, given the prior literature on child participation in medical discussions (Tates and Meeuwesen, 2000). The United States Pharmacopeia suggests that children be included in discussions about their medications and there is literature supporting how to

encourage children to become involved in their medication discussions (Bush et. al. 1999).

Children around seven years old can begin to understand cause and effect relationships on their health (Sleath et. al. 2003). The US Pharmacopeia (Bush et. al. 1999) takes the stance that children should be taught about their medications and involved in their medication discussions. Further, studies have shown that even with adult patients, most of the information that is given during the medical consultation is forgotten (Kessels 2003). While children would hardly know about the risks of their medications without first being taught by their medical providers and caregivers, medical providers should use the Teach-Back method (DeWalt et. al. 2010) to aid child recall of the important points that are discussed during the visit. Asking children to repeat the potential risks of their medications in their own words could increase their understanding of the use of their medications.

More than one-third of caregivers also reported a problem/concern about side effects of their child's asthma control medication one month after the audiotaped visit. There were only 11 visits, however, in which caregivers asked a question about asthma control medication risks and eight visits in which caregivers made statements about the risks of their child's asthma control medication. Like children, caregivers are not discussing the risks and side effects of their child's asthma control medication with providers very often. This could mean that providers are not fully explaining the risks of asthma control medications with caregivers and therefore are not lessening caregiver's concerns. Using

the Teach-Back method with caregivers as well as children when discussing risks may be beneficial in helping caregivers understand the risks associated with asthma control medication use. This understanding may lead to a fewer percentage of caregivers reporting problems/concerns with side effects, but should be studied further.

Also, providers rarely addressed each of the dimensions that Bogardus describes as essential elements of risk communication. Specifically, providers only discussed the probability of the child experiencing a risk during 3% of encounters (N=8). However, only one provider used numbers to convey the probability of a risk occurring. Prior research has found that using words to convey probability information may be misleading (Berry, et. al. 2003) because consumers may not have an anchoring to a specific word that may be used. When describing probability information, providers need to use a format that is easily understood by even those with limited numerical skills. The use of numerical formats such as percentages or absolute risk reduction may be helpful to caregivers so they can understand the probability of their child experiencing a risk (Sheridan et. al. 2003).

There have been previous studies that have examined how providers discuss probability information and how patients understand that information. Neuner-Jehle and colleagues (2011) found that providers used qualitative methods of explaining risk probability, however patient understanding was higher when the provider used visual aids, such as graphs, to describe risk probability. This study confirms Neuner-Jehle and colleagues finding because providers in this dissertation used qualitative expressions of probability

most often. Providers could enhance patient understanding of probability by using graphs.

Discussions of risks were significantly more likely when children were taking or prescribed an inhaled corticosteroid. Inhaled corticosteroid risks, such as reduced final adult height, are prevalent throughout the American popular media. In spite of the much-publicized risks, inhaled corticosteroids are often the first line of therapy when managing persistent asthma. The national asthma guidelines state that while ICS medications may pose risks, such as oral thrush and short-term decreased velocity of child growth, the benefits of using the medication outweigh those risks (NAEPP, 2007).

Finally, visits that were longer were associated with a significantly increased likelihood of discussing asthma control medication risks. Given the demands of a primary care pediatrician's time, increasing visit time for medication risk discussions may not be an attractive finding. However, shorter visit time has been cited as a barrier to effective healthcare communication and shorter visits are associated with worse patient outcomes (Cox et. al. 2007). In this aspect, pharmacists can help educate children and caregivers about the risks of asthma control medications. Additionally, pharmacists can teach children and caregivers how to use the asthma medication correctly to reduce the chance of risks occurring. More research is needed on whether discussions of medication risks lead to longer medical visits and improved outcomes.

It is worth noting that providers who classified themselves as physician assistants, nurses, and nurse practitioners did not have any visits in which there was a risk discussion. This is an important finding of this study. There may be two explanations for this finding: (1) providers who are not physicians may lack the self-efficacy to fully discuss risks of asthma control medications; and (2) there may be a different type of provider-patient relationship between physician assistants and nurse practitioners with caregivers and children. Both of these hypotheses merit further research. The second hypothesis has some validity in our data because neither caregivers nor children asked any questions nor made any statements about medication risks with non-physician providers.

Discussions of asthma control medication risks were significantly more likely to occur when providers were starting a new prescription for an asthma control medication. It is concerning however, that risks were significantly less likely to be discussed when the provider continued a previous prescription without making any changes to the dose or the directions. Providers need to have an ongoing dialogue with children and their caregivers and ask about any medication risks. There are some medication-related risks associated with asthma control medications that are constant risks, such as the risk for oral thrush. Repeating important discussion points often and using the Teach-Back Method when discussing medication-related risks may increase the possibility of a child adhering to behaviors that may reduce the chance of a risk occurring, i.e. rinsing out the mouth after using an asthma control medication and using a spacer with inhalation devices.

Discussions about Benefits of Asthma Control Medications

Asthma control medication benefits were discussed in less than half of the medical visits (47.1%). Provider discussions about benefits were the most diverse across all communication areas that were studied. Providers asked questions in eight different areas of benefit. When providers made statements about benefits of asthma control medications, they made statements in 20 different areas.

Children's participation in the communication was highest during discussions about medication benefit. Nonetheless, children only spoke about asthma control medication benefits in four percent of visits. Providers and caregivers need to encourage children to participate in the discussion because more involvement from children in medical visits has been associated with better health outcomes (Cox et. al. 2007). Other research shows that caregivers interfere when providers ask children questions (Tates and Meeuwesen, 2000). Future research should investigate how caregivers can let children speak during the medical visit while at the same time allowing full interaction between the provider and caregiver.

The GEE results showed that children who were younger were significantly more likely to have a visit that included a discussion about asthma control medication benefits. Previous studies have found that child participation in medical visits increases with age (Tates and Meeuwesen 2002; Cox et. al. 2009). Providers need to discuss the role and benefits of asthma control medications with every child and caregiver to ensure understanding.

Asthma control medication benefits were also significantly more likely to be discussed when asthma control medication risks were discussed. This could mean that when asthma control medication risks are discussed during a medical visit the provider also discusses the positive aspects of the medication, the benefits of the medication.

Discussing and educating children and caregivers about the risks and benefits can lead to better child and caregiver involvement in medical decisions or shared decision-making (Makoul and Clayman 2006). However, discussions of medication risks were relatively infrequent and approximately 12% of medical visits had discussions of both risks and benefits together. Discussions of medication risks need to improve both in content and frequency to lead to better child and caregiver involvement.

Visits that included a discussion about adherence were also significantly more likely to include a discussion about medication benefits. The qualitative examination found that providers spoke about the benefits of medication adherence. National practice guidelines for asthma encourage providers to screen for asthma medication adherence at every visit. There were visits in our study where providers asked children if they used their control medication on a consistent basis. Providers can educate children and their caregivers that control medications are most effective when used daily and discuss the benefits of adherence more often. This may lead to fewer misunderstandings about the role of asthma control medications for caregivers and children (NAEPP, 2007).

Finally, discussions about control medication benefits were significantly more likely when children were taking or prescribed an inhaled corticosteroid. This finding could mean that children who take or prescribed an inhaled corticosteroid may be more likely to have visits that include discussions about risks and benefits. Future research should investigate whether being prescribed an inhaled corticosteroid leads to discussions of medication risks and benefits.

Benefits were significantly more likely to be discussed when a new medication was started. Eighty percent of information that is discussed during medical visits may be forgotten immediately after the visit (Kessels, 2003) and providers need to ensure that both children and their caregivers understand the reason (s)he is using a certain medication. Using the Teach-Back method to ensure child and caregiver comprehension and repeating important points often are a necessary and essential component of discussions about medication-related benefits.

Caregiver-Reported Adherence to Asthma Control Medications

Fifty-nine percent of caregivers reported their child as having an average adherence score of at least 80%. This means that more than 40% of caregivers in this sample classified their child as non-adherent to asthma control medications. The mean adherence score that caregivers reported was 84.6% with a range of 0%-100%. Previous studies have found that adherence to asthma control medications has wide variability (Rau, 2005). Previous studies have also shown that self-reported medication adherence measures are consistently higher than when measured by more objective measures, such as pharmacy

refill records or electronic monitoring devices (Rau, 2005). This study's finding of an 84.6% average adherence score could be at least partially due to self-report bias.

However, since children as young as nine years old use their asthma control medications without adult supervision it is possible that caregivers are not fully aware of their child's medication use (Orrell-Valente et. al. 2008). Future research should determine if children's self-report of adherence is related to more objective measures of adherence to verify the accuracy of self-reported medication use by children.

Caregivers were significantly more likely to classify their child as 80% or more adherent to their asthma control medications when the child took a higher number of asthma control medications. This finding is surprising given that prior studies have found that medication regimen complexity, such as having more medications to take, was related to poorer adherence (Rau, 2005). The result could be due to self-report bias and future research should use more objective measures to determine patient adherence. The result could also be because caregivers of children that were more adherent to asthma control medications were more likely to enroll in the parent asthma study. As stated earlier, future research should use more objective measures of child adherence to determine whether children are as adherent as they seemed to be in this study.

Caregivers were also significantly more likely to classify their child as 80% or more adherent to their asthma control medications when the length of the visit was longer. Previous studies have found that shorter medical visits are associated with worse outcomes, a finding that this study corroborates (Cox et. al. 2007). Also, prior research

has found that patient trust in their medical provider increases with the length of time the provider spends with the patient (Fiscella et. al. 2004). Therefore, it is important that providers spend time with their patients to increase medication adherence in asthma as well as help build patient trust.

Caregivers were significantly more likely to classify their child as 80% or more adherent to their asthma control medications when the child had seen the study provider more times. Previous studies have found that patient trust in providers is correlated with the number of times the patient has seen the provider (Hall et. al. 2002). More research needs to be done to examine whether caregiver trust in their child's medical provider is associated with the number of times that the child has seen the provider.

An interesting finding is that a discussion about control medication adherence during the medical visit was not associated with caregiver-reported adherence one month later. Simply discussing adherence of asthma control medications may not be enough of an intervention to improve medication adherence, based on the results of this study.

Discussions about medication-related side effects, risks, and benefits were not significantly associated with caregiver-reported asthma control medication adherence of at least 80% in this study. This could be because of the very high average adherence that was reported by caregivers or it could be that discussions about medication risks and benefits are only one aspect of a behavior (i.e. medication adherence) that is complex and can change on a daily basis, regardless of whether side effects, risks, or benefits were

discussed during a medical visit. Previous research has shown that intention to adhere to medications is associated with discussions about medication-related risks (Thurmann 2006). Future research should examine whether there is a relationship between intention to adhere to asthma control medications and problems/concerns about side effects of medications to determine if patients or caregivers who score higher on an intention measure would be less likely to report a problem or concern about side effects.

Caregiver-Reported Problems and Concerns About Side Effects with Child's Asthma Control Medications

A significant proportion (37%) of caregivers voiced concerns about side effects from their child's asthma control medications one month after the medical visit. However only 11 visits included caregivers asking questions about control medication risks. Therefore there are a substantial proportion of caregivers who are not voicing their concerns or problems with side effects to their child's provider. Previous research has found that most nonadherence originates in personal beliefs or concerns about asthma that have not been discussed with a medical provider (Bender and Bender 2005). Our study confirms that a significant proportion of caregivers have personal concerns about side effects of their child's asthma control medication, yet did not discuss these concerns during the medical visit. Providers can encourage caregivers to speak about their concerns by asking: "What worries you most about your child's asthma medications?" (NAEPP, 2007).

The bivariate and GEE results showed that when caregivers reported their child had fewer previous visits with the study provider, they were significantly more likely to

report a problem and concern with side effects one month after the study visit. This finding is an important contribution of this study. Prior research has shown that the length of time that a patient has been with a provider is significantly associated with trust in the provider (Hall et. al. 2002). Our study did not examine other aspects of trust in physicians, but future research should in order to determine if trust is related to caregiver's concerns with their child's asthma control medications.

Another interesting aspect to this study's findings shows that caregivers were more likely to be adherent when the child had more visits with the study provider and less likely to have a problem or concern about side effects when the child had seen the provider more times. These findings together add credence to the theory that trust in medical providers is a significant aspect of medical care. More trust in providers may lead to better asthma outcomes, but this relationship needs to be studied further to assess the relationship of trust with less problems or concerns about side effects and medication adherence.

Similar to the caregiver-reported adherence measure, discussions about side effects, risks, and benefits were not significantly associated with the level of caregiver-reported problems and concerns about side effects one month after the visit. It could be that we assessed the wrong time point to understand if there was a relationship between caregiver-reported problems and concerns about side effects and discussions about medication-related side effects, risks, and benefits. Future research should examine whether discussions about side effects, risks, and benefits are associated with caregiver-

reported problems and concerns about side effects immediately after the medical visit (Kessels 2003).

Child-Reported Problems and Concerns about Side Effects from Asthma Control Medications

Like their caregivers, more than 32% of children reported a problem or concern about side effects of their asthma control medications. Yet, only three children asked questions about asthma control medication risks and only three children made statements about the side effects of their asthma control medications during the medical visit. Thus, a substantial proportion of children are not discussing their concerns or problems with side effects with their medical providers. Children need to be taught to participate in their medical encounters, especially since their participation improves disease self-management and increases both parent and child satisfaction with their medical care (Cox et. al. 2009).

Providers can encourage discussions about the concerns of children in using asthma control medications by directly asking the child: “What concerns you most about your asthma medication?” (NAEPP, 2007). National practice guidelines recommend that providers start each visit by asking about the patient’s asthma concerns, including medications (NAEPP, 2007). It is important for providers to discuss children’s concerns using asthma control medications so that those concerns can be identified and addressed (NAEPP, 2007).

Children who did not take inhaled corticosteroids were significantly more likely to be concerned about side effects of their asthma control medication(s). Future research should try to determine why this finding occurred. One hypothesis is that children who are prescribed Singulair may experience more side effects than children who take inhaled corticosteroids or because the child could be using a rescue medication more often. Future research should not only determine if children have concerns about side effects, but also ask specifically which side effects that children are most concerned about. Based on this, future research also needs to examine if there are more instances of side effects with Singulair than with inhaled corticosteroids, as well as if children who have persistent asthma who do not take inhaled corticosteroids experience more side effects because of using rescue medications more often.

Children were also significantly more likely to report a problem or concern about side effects from their daily asthma medications when their caregiver was not married. Previous research shows that married caregivers exert a positive effect on children's negative attitudes toward medications. Rhee and colleagues found that family support was found to reduce adolescents' negative attitudes toward medication (Rhee et. al. 2010), which also increased adherence. DiMatteo (2004) found that marital status increased medication adherence. Furthermore, children who are from divorced caregivers may experience more negative aspects of asthma medication use because of the child not using their asthma medication while at the other caregiver's home. It could also be that single caregivers have less time to focus on a child using an asthma control

medication. Future research should investigate the problems with using asthma control medications that single caregivers face with their children.

Finally, children whose providers were male were significantly more likely to report a problem or concern with side effects. This finding is surprising and shows that provider characteristics may be associated with children's concerns about side effects. Our study did not find any differences in physician gender regarding visit length, and when side effects, risks, and benefits were discussed. Previous studies have found that female providers have longer visits, engage in more social exchange and encouragement (Bernzweig et. al. 1997). Caregivers may be more likely to be satisfied with female providers (Bernzweig et. al. 1997). Future studies should investigate other communication factors that may be involved in children having concerns about side effects of their medications.

It is important to note that discussions about asthma control medication side effects, risks, and benefits were not significantly associated with child-reported problems and concerns about side effects one month after the medical visit. Similar to caregivers, we may have assessed the incorrect time point to recognize if there was a significant relationship with discussions about side effects, risks, and benefits and child-reported problems and concerns with side effects of asthma control medications. Future research should examine whether discussions about side effects, risks, and benefits are significantly associated with child-reported problems and concerns immediately after the medical visit.

Implications

Communication about medication side effects, risks, and benefits are important features of medical visits between children with asthma and their caregivers and their medical providers. Provider-patient communication is a multifaceted concept with implications for patient care.

Active discussion about medication side effects, risks, and benefits during the prescription medical visits may have several benefits. First, it may increase the likelihood that providers and caregivers and children will agree on a course of treatment. Second, engaging patients in the side effect, risk and benefit discussions may decrease concerns about using asthma control medications. Third, studies have shown that for children and caregivers alike, concerns and negative attitudes toward asthma control medication seem to influence medication use (Le et. al. 2008, Conn et. al. 2007 and Conn et. al. 2005). Initiating conversations about medication use in relation to side effects, risks, and benefits give providers an opportunity to identify and address concerns that children and caregivers may have regarding using an asthma control medication.

Inhaled corticosteroids were the most often used when treating children with persistent asthma. The strong association between discussion of risks and benefits and the child taking or being prescribed an inhaled corticosteroid may indicate that there is a general public wariness to the safety of inhaled corticosteroids, therefore caregivers and providers need to discuss both the pros and the cons of the medication.

Encouraging medical visit communication that enables child involvement may be more likely to result in a better understanding of medication benefits and risks from the child's point of view. Children can learn when to take the medication, how to take the medication, why to take the medication (benefits), and why they should not take more of the medication to feel better (risks). Emphasizing the side effects, risks, and benefits of the child's asthma control medication may further help the child become acculturated to better provider-patient communication as the child ages.

The results of this study also showed a clear association of familial support on children's perception of the side effects of asthma medications. Providers can recognize that children from single-caregiver families may be at a higher risk for concerns about side effects from their asthma control medications. Providers should be especially vigilant about screening children with single-caregiver families, by not only asking the child and the caregiver if the child has been taking the medication, but also if the child has any concerns about side effects from the medication, which the national guidelines also state that providers should do (NAEPP, 2007). In addition to asking the child questions about concerns about side effects (s)he may have, the provider can openly and thoroughly discuss the possibilities of side effects other than the specific concerns that the child may have. Providers not only need to discuss specific risks, but also the timing of the risk, the permanence of the risk, the probability of getting the risk, and ensure the child is comfortable with the risks (Bogardus et al. 1999). Providers also can help to prevent medication-related risks by teaching children better inhalation technique and prescribing spacers for inhalers for all children, as stated by the national guidelines (NAEPP, 2007).

Finally, continuity of care may be an important factor in how caregivers perceive their child's medical care as well as improving health outcomes (Christakis et. al. 2002). Making efforts to improve continuity of care may be an essential factor in reducing caregiver's concerns about their child's asthma control medications, in addition to improving the perception of quality of medical care and caregiver trust in the provider. Improving all of these aspects of health care in the medical clinic may also improve medication-related outcomes, such as asthma control medication adherence.

This study's results also have implications for pharmacists. Pharmacists are often the last medical provider that patients see when they obtain physical control of their medication. Patients can ask pharmacists in-depth questions about the medications and the pharmacists can discuss the medication's risks and benefits while also monitoring adherence, and concerns about the medication that may lead to decreased adherence. Clinics may be able to employ pharmacists in medical clinics to review medications before children see their provider. The pharmacist can ask about side effects and can discuss risks and benefits of the medication with children and their caregivers. The pharmacist can then enter the results of those discussions directly in the child's medical chart so the provider can review the pharmacist consultation.

When speaking with patients, pharmacists can discuss the medication's risks and benefits with both caregivers and children as well as concerns about using the medication. Pharmacists may be able to improve adherence to asthma medications by addressing

concerns about the medication. Pharmacists can also discuss ways to mitigate the onset of risks, such as discussing ways to prevent risks. Pharmacists can also ask children and caregivers about whether the child had experienced side effects at every refill. By opening lines of communication with not only the caregiver but also the child, the pharmacist can provide a direct link to the child's provider if the child does experience a side effect that needs to be treated, such as oral thrush.

Study Limitations

This study has several limitations. First, we examined only children with asthma and primary care pediatric providers. Therefore, the results may not be generalizable to other patient populations or provider specialties. Persistent asthma is, however, an excellent model to study medication side effects, risks, and benefits because it is both a symptomatic and asymptomatic condition that requires daily medications. Second, both patient and provider samples were convenience samples and self-selection biases are possible. Third, some categories of the outcome variables of interest were smaller than the full sample size, because of non-responders and patients who declined to perform the home visit part of the study. This study was, however, still sufficiently powered to detect meaningful differences. Fourth, measurement of the full set of factors that affected communication and medication concerns about side effects may not have been examined by this study. There may be mediating variables that affect the relationship between provider-child-caregiver communication as well as medication adherence and concerns/problems with side effects of asthma control medications.

Fifth, the presence of the tape recorder may have altered provider and patient behavior during the medical visit, although this seems unlikely to significantly affect the conclusions since the data were collected for another purpose. Providers, children, and caregivers were blind to the research hypotheses for both the parent study and the current study, reducing the likelihood that they would have altered their behavior in the areas of medication side effect, risk, and benefit communication.

Finally, previous research on attitudes toward asthma control medications has consistently found an association between concerns about asthma control medication leading to decreased adherence. The finding that reported concerns about side effects was not associated with significantly decreased adherence in either caregivers or children may be at least partly due to social desirability bias. Prior research has found that subjective measures of asthma control medication adherence such as self-report is higher than objective measures, such as canister weight and pharmacy records (Jentzsch et. al. 2009). Additionally, children use their own asthma control medications without supervision as young as nine years old (Eggleston 1998). When young children supervise their own medication use, caregivers may be less likely to know exactly how often the child uses the asthma control medication, therefore limiting the complete usefulness of using caregiver self-report of a child's medication adherence. Future research should use objective measures of adherence, such as pharmacy refill records or electronic monitoring.

Study Strengths

Notwithstanding the limitations, this study has several strengths and makes an important contribution to the knowledge base about medication side effect, risk, and benefit communication in pediatric medical visits. First, this study is the first to examine communication about asthma control medication side effects, risks, and benefits in a population of children with persistent asthma. Second, this study is the first to look simultaneously at medication side effect, risk, and benefit communication and asthma control medication adherence. Third, the study looked at the actual medical visit communication about side effects, risks, and benefits, providing a deeper understanding of the content of such communication than has previously been reported. The findings of specific categories of statements and questions add to the literature as well. Fourth, the use of both qualitative methods and quantitative methods permitted examination of both the content of medical visit communication and predictors of communication and outcomes. Finally, the study provides practical guidance for clinical practice by identifying a strong relationship between children taking or being prescribed inhaled corticosteroids and control medication risk and benefit communication. Through open communication and providers engaging the child during the medical visit, medication adherence and concerns about side effects can be addressed in the medical visit.

Directions for Future Research

Both the implications and limitations discussed above suggest a number of future directions for research on medical visit communication about asthma control medication side effects, risks, and benefits. First, the types of communication about medication side

effects, risks, and benefits may serve as a useful starting point for designing studies looking at the different constructs of side effects, risks, and benefits in pediatric and adult asthma. Future studies examining the content of communication about asthma control medication side effects, risks, and benefits in a larger sample of patients with persistent asthma would provide insight into whether or not the concepts are consistent across samples.

It is important to note that not all discussions about side effects and risks are equal. Future research should examine the quality of the discussions about side effects and risks. Future research could use a weighted scoring method to evaluate the quality of the discussions based on a theoretical framework, such as Bogardus. Higher scores would be reflective of better quality discussions. The quality of the discussions could then be used in a multivariate model to determine whether the quality of the discussion is related to asthma control medication adherence as well as caregiver- or child-reported problems and concerns about side effects of asthma control medications.

Another feature that is related to quality of discussions is the amount of time that is spent discussing medication-related side effects and risks. While this study did not examine the amount of time that providers spent discussing side effects and risks, this aspect should be examined in order to understand if the amount of time that is spent discussing side effects and risks is associated with appropriate asthma control medication adherence as well as caregiver- and child-reported problems and concerns about side effects of asthma control medications. Future research should also focus on the amount of time that

providers spend discussing medication-related benefits. Future research should examine whether providers spend more time discussing benefits than side effects and/or risks as well as if this difference is associated with adherence and problems/concerns about side effects.

Next, an intervention that would be beneficial in improving discussions of medication-related risks and shared decision-making could be designed following Elwyn and colleagues 2004 study in Great Britain (Elwyn et. al. 2004). This study showed that providers were able to increase their use of shared decision making as well as risk communication by providers attending a shared decision making workshop and a risk communication workshop.

An intervention that followed Elwyn's study design could be applied to providers who treat children for persistent asthma. A study could be designed to audiotape a particular number of providers who treat children with asthma. After a group of children were initially enrolled into the study, providers could be randomly assigned to a risk communication workshop. The providers who were not randomly selected into the workshop would continue to treat their patients with usual care. In the workshop, particular attention would be paid to increasing provider awareness of Bogardus' dimensions of risk communication. Providers would be taught to discuss specific risks, their probabilities, timing, and permanence of the risks. Providers would also be taught to ask caregivers and children their feelings about the risks of each asthma control medication. An outcome measure could be the amount of providers who increased the

frequency of risk discussions among their patients as well as examining adherence in the study group versus the usual care group using pharmacy refill records.

Also, future studies could examine which risks children want to discuss in medical visits as well as the risks that caregivers want to discuss in medical visits. A promising study that was led by Raynor and colleagues (Raynor et. al. 2004) showed that children as young as 12 years old had certain medication information needs that providers should address when talking about asthma medications: (1) name and the purpose of the medication; (2) when to take it, how to take it, and how long to take it; (3) side effects and what to do about them; (4) interactions with other medications; and (5) how to tell if the medication is not working. Incorporating those five sections of medication discussions into an intervention could be beneficial in enhancing risk communication.

An intervention that incorporated Raynor's 2004 study could be audiotape recording pharmacist discussions with children who have persistent asthma. The pharmacist would have a checklist of each important topic area from Raynor and colleagues (2004) each time they interacted with a study patient. By randomly selecting pharmacists into a discussion using Raynor's topic areas and comparing with pharmacists who continue to see their patients as usual care, researchers could examine child adherence among the study arm pharmacists and the control group pharmacists.

Next, the audiotaped medical visit that was used in the present study provided only a snapshot of the provider-child-caregiver relationships. Using a longitudinal study design

would permit the assessment of investigating side effect, risk, and benefit communication on medication adherence over multiple medical visits. Longitudinal study designs in future research should attempt to identify important mediators and moderators of communication about side effects, risks, and benefits of asthma control medications and the impact of these communications on patient outcomes. Caregiver's and children's trust in their providers, provider attitudes with side effect, risk, and benefit communications, and caregiver's and children's assessments of their willingness to take a medication given certain risks and benefits are just some of the factors that may mediate or moderate the relationship between communication and patient outcomes.

Future studies should include both observational and perception measures of communication. Direct observation of communication permits reliable assessment of the content and time spent discussing certain topics, but it fails to capture whether children and caregivers understood the information provided. Given that prior research has found that most patients forget the information their provider discussed during the medical visit and those who remember the content are incorrect when they have to recall the information (Kessels 2003), it is important for researchers to understand if both children and caregivers understand the side effect, risk, and benefit communication that providers may give them during a medical consultation. An intervention that included the Teach-Back method would be especially beneficial in helping children and caregivers understand the information that is presented during a medical visit.

Providers could incorporate the Teach Back method in their discussions about medication-related risks and benefits. A study that could be designed would be where providers are audiotape recorded and there would be a nurse in the room to act as a health advocate. There would be providers who would continue to treat children as usual without the health advocate in different practices. The health advocate could ensure that providers use the Teach Back method during the clinic visits. Researchers could then assess if using the Teach Back method resulted in more accurate recall of what was discussed during the medical visit.

Future studies should also examine provider attitudes toward discussing side effects, risks, and benefits with a particular focus on self-efficacy. Related to self-efficacy, future research should focus on the knowledge that primary care providers have about medication-related side effects and risks of asthma control medications. Our results showed that providers who were not physicians did not have visits in which asthma control medication-related risks were discussed. Future research should try to determine if there is a difference in self-efficacy and knowledge among providers who are not physicians and providers who are physicians.

Additionally, future research should also examine how children can be taught to effectively participate in their medical encounters, especially in discussing medication risks and benefits. Interventions should be aimed at children that take into account a child's cognitive stage as well as their age. Since there is a high prevalence of adults with low numeracy in the United States, interventions that can be tailored for low

numerate adults have the potential to be used in children as well. An example of an intervention that has the potential to be used by children and their caregivers could be teaching a medical provider to discuss each of Raynor's five areas of medication information (Raynor et. al. 2004), with both children and their caregivers, using the Teach-Back method. A randomized controlled trial that compares usual care with this intervention may be useful in not only making children and their caregivers aware of their asthma medication and the risks and benefits associated with using it, but also increase comprehension of that information.

An intervention should also be tested that examines how pharmacists can discuss medication-related risks and benefits to children and caregivers. Pharmacists have a limited time to counsel patients on their medications. Utilizing Raynor and colleagues framework to discussing asthma medications may be beneficial for pharmacists (Raynor 2004). The intervention could be a simple workshop that teaches pharmacists to counsel patients by discussing: (1) name and the purpose of the medication; (2) when to take it, how to take it, and how long to take it; (3) side effects and what to do about them; (4) interactions with other medications; and (5) how to tell if the medication is not working. Another possible intervention that could be directed at pharmacists is a course that specifically targets pharmacy rotation students and teaches important communication aspects, incorporating Raynor and colleagues' findings of talking points when discussing medications with children and caregivers and using the Teach-Back method to ensure understanding. The intervention could end with simulated patients and discussions of ways in which pharmacists can enhance their discussions with children and caregivers.

Conclusion

This study helps address gaps in the literature regarding communication between providers and children and their caregivers about asthma control medication side effects, risks, and benefits. While the literature has stressed the importance of provider-patient communication about medication risks, this was the first study to examine the content and predictors of actual discussions about asthma control medication side effects, risks, and benefits. Our results show that providers rarely discuss side effects and risks of asthma control medications with children and caregivers. Our results also show that discussions about asthma control medication benefits do not occur in every visit, but comparatively more so than side effects and risks. Physicians were the only providers who had visits in which asthma medication risks were discussed and asked questions about asthma control medication benefits.

Study results indicate that medication side effects, risks, and benefit communication are complex topics that take many different forms in routine medical visits. The study results may facilitate the development of interventions that focus on children, caregivers, and providers to encourage discussions about asthma control medication side effects, risks, and benefits in primary care medical practice. Interventions utilizing technologies to bring child-reported concerns about side effects and medication adherence to the point of care may go a long way to improving the communication about asthma control medication side effects, risks, and benefits. This study may also help provide a framework for providers to start discussing the potential risks that children face in other chronic diseases that require daily medication management.

Appendix A: Asthma Control Medications

Generic (Brand name)

Inhaled Corticosteroids

Beclomethasone (Vanceril®, Beclovent®, Qvar®)

Triamcinolone (Azmacort®)

Flunisolide (Aerobid®)

Fluticasone (Flovent®)

Budesonide (Pulmicort®)

Mometasone (Asmanex®)

Anti-inflammatory: Mast-cell stabilizer

Cromolyn (Intal®)

Nedocromil (Tilade®)

Long-acting beta agonist

Salmeterol (Serevent®)

Formoterol (Foradil®)

Inhaled corticosteroid and long-acting beta agonist

Salmeterol and fluticasone (Advair® diskus)

Methylxanthines

Theophylline (Slo-bid®, Theo-Dur®, Uniphyll®)

Leukotriene Modifiers

Zileuton (Zyflo®)

Zafirlukast (Accolate®)

Montelukast (Singulair®)

Appendix B: Supplemental Coding Instrument

Supplemental Coding Instrument

Patient ID: _____

Coder ID: _____

Date of Coding: _____

Asthma Proposal – Supplemental Coding Instrument

i). Is there more than one caregiver present
during the audiotaped medical visit?

Y N

1.

a. Name of Control Medication Discussed	b. End of Visit Plan	c. Risks Discussed	d. Side Effects Discussed	e. Benefits Discussed
	Start Cont	Y N	Y N	Y N
1 _____	D/C	N/A	N/A	N/A
	Start Cont	Y N	Y N	Y N
2 _____	D/C	N/A	N/A	N/A
3 _____	Start Cont	Y N	Y N	Y N
_____	D/C	N/A	N/A	N/A
4 _____	Start Cont	Y N	Y N	Y N
_____	D/C	N/A	N/A	N/A

2.

Side Effects	Yes	No		
a. Are side effects discussed?	Y	N		
b. If yes, for what asthma control medication(s)?	1	2	3	4
c. If yes, who initiates the discussion?	C	P	D	N/A
d. Does caregiver or patient state experience of side effects?	C	P	D	N/A

Name of Side Effect Discussed
1 _____
2 _____
3 _____
4 _____
5 _____
6 _____
7 _____
8 _____
9 _____

2e. Number of caregiver questions about side effects? _____

2f. Number of caregiver statements about side effects _____

2g. Number of child questions about side effects? _____

2h. Number of child statements about side effects _____

2i. Number of provider questions about side effects? _____

2j. Number of provider statements about side effects _____

3.

Risks	YES	NO		
a. Are risks discussed?	Y	N		
b. If yes, who initiates?	C	P	D	N/A

c. Identity of risk discussed	d. Is Permanence Discussed	e. Is Timing Discussed	f. Is Probability Discussed	g. Are Values Discussed	h. Is Severity of Risk Discussed
1 _____	Y N	Y N	Y N	Y N	Y N
_____	N/A	N/A	N/A	N/A	N/A
2 _____	Y N	Y N	Y N	Y N	Y N
_____	N/A	N/A	N/A	N/A	N/A
3 _____	Y N	Y N	Y N	Y N	Y N
_____	N/A	N/A	N/A	N/A	N/A
4 _____	Y N	Y N	Y N	Y N	Y N

—	N/A	N/A	N/A	N/A	N/A
5	Y N	Y N	Y N	Y N	Y N
—	N/A	N/A	N/A	N/A	N/A
6	Y N	Y N	Y N	Y N	Y N
—	N/A	N/A	N/A	N/A	N/A
7	Y N	Y N	Y N	Y N	Y N
—	N/A	N/A	N/A	N/A	N/A
8	Y N	Y N	Y N	Y N	Y N
—	N/A	N/A	N/A	N/A	N/A
9	Y N	Y N	Y N	Y N	Y N
—	N/A	N/A	N/A	N/A	N/A

3i. Does provider discuss probability qualitatively? Y N N/A

3j. Does provider discuss probability numerically? Y N N/A

3k. Number of caregiver questions about risks? _____

3l. Number of caregiver statements about risks _____

3m. Number of child questions about risks? _____

3n. Number of child statements about risks _____

3o. Number of provider questions about risks? _____

3p. Number of provider statements about risks _____

4.

Benefits Discussed	YES	NO		
a. Are benefits discussed	Y	N		
b. If yes, who initiates?	C	P	D	N/A

c. Names of Benefits Discussed
1 _____
2 _____
3 _____
4 _____
5 _____

6	_____
7	_____
8	_____
9	_____

4d. Number of provider statements about benefits of asthma control medications _____

4e. Number of provider questions about benefits of asthma control medications _____

4f. Number of caregiver statements about benefits of asthma control medications _____

4g. Number of caregiver questions about benefits of asthma control medications _____

4h. Number of patient statements about benefits of asthma control medications _____

4i. Number of patient questions about benefits of asthma control medications _____

Appendix C: Coding Rules for Supplemental Coding Instrument (SCI)

Coding Rules for Supplemental Coding Instrument (SCI)

All questions contained in the SCI about risks, side effects, and benefits of medication are for asthma control medications only. Follow these rules for coding of the instrument in the order directed by this document.

Notes about Medications:

- For the purposes of this study, we are interested in medications that are used to treat persistent asthma.
 - You have been provided with a sheet that contains all of the asthma control medications that are used to treat persistent asthma.
- Medication conversations that are of interest include medications the child is taking, has taken, or may take.
 - This includes medications that the patient should have been taking since their last visit, medications the patient has stopped taking, new medications that are being prescribed during the visit, and medications that are to be started that is contingent on a certain circumstance, medications that are being considered, and/or medications that are mentioned.
 - This also includes medications that the patient is taking regardless of whether or not they were prescribed by the provider that was recorded in the transcript.

Asthma Control Medication Side Effects, Risks, and Benefits:

- Conversations about asthma control medication side effects, risks, and benefits includes direct communication about these concepts. Direct communication involves explicit communication about the side effects, risks, and benefits that the patient may be or has experienced as a result of using the medication.
- For the purposes of this study, we have defined side effects, risks, and benefits that are to be followed **CLOSELY**:
 - **Side Effects:** Side effects are defined as adverse effects that the patient HAS experienced as a result of using the asthma control medication.
 - Side effects' definition DOES NOT include adverse effects that the patient may experience, regardless of whether the provider, child, or caregiver uses the direct words "side effects."
 - *Example:* C-I took his Singulair away he has not complained to me about headaches.
 - **Risks:** Risks are defined as adverse effects that the patient HAS NOT experienced yet or MAY experience as a result of using the asthma control medication.
 - Risks' definition DOES NOT include adverse effects that the patient has already experienced.
 - *Example:* D: The steroids don't make you grow hair and muscles it's just anti-inflammatory, just for lungs.

- o **Benefits:** Benefits are defined as ANY positive effects that the provider, child, or caregiver discusses that are results of using the asthma control medication. This includes discussions of prior benefits or benefits that have not been experienced yet
 - *Example:* D-...We should be able to get him on enough medicine that you are able to play soccer and run and to not get that short of breath

When Coding:

1. Use your computer's Microsoft Word software to code the information on the coding tool
- 1.
2. Please have the asthma control medications sheet during the entire coding process.
- 2.
3. Read the transcript at least 3 times in order to correctly code the visit
 - a. Use the first time as a way to get acquainted with the transcript and learn how the communication process works
 - b. Use the second time to code information that is contained in the following pages. There is a high likelihood that you will not be able to capture all the information during the second reading.
 - c. Use the third time to capture the information you may have missed during the second reading, and to verify that you have followed the rules for coding.
4. Make sure that **each item** and category is coded (highlighted in Microsoft Word) appropriately. Please double-check your work.
5. Generally, more information is always preferred. If you are unsure about how to code an interaction, record as much detail about the encounter and record any notes or questions that may be helpful in determining why a particular decision was made.

To Code:

Header: Transcript Identification, Coder Initials, and Coding Date

3.
 - **Transcript/Patient Identification Number:** Be sure to type the patient's 5-digit identification number. The format should be:
 - o *Example:* 010101
 - 010101 is the patient ID number for the project.
 - The first two digits identify the clinic, the second two digits identify the provider, and the last two identify the patient.
 - In this case, at clinic 01, provider 01 is seeing patient 01.
 - **Coder Initials:** Type your initials here.
 - **Date Coded:** Record the current date on which you are coding the transcript.
- 4.

Initial Page Content

Legend

Y = 'yes'

N = 'no'

D = 'doctor'
P = 'patient/child'
C = 'caregiver'
Ne = 'neither'
N/A = 'not applicable'

Question i – Code this question as 'Yes' if the top right hand side of the transcript indicates that there was more than one caregiver present during the visit. This includes O for other, but not for siblings.

Name of Control Medication Discussed	End of Visit Plan	Risks Discussed	Side Effects Discussed	Benefits Discussed
1 _____ =	Start Cont D/C	Y N	Y N N/A	Y N
2 _____ =	Start Cont D/C	Y N	Y N N/A	Y N
3 _____ =	Start Cont D/C	Y N	Y N N/A	Y N
4 _____ =	Start Cont D/C	Y N	Y N N/A	Y N

For **Name of Control Medication** box above, write the name of *each* of the asthma control medications discussed during the medical visit.

Then, for the **End of Visit Plan** box code whether the provider *Started, Continued, or Discontinued (D/C) the medication*. If the provider changes the dose of a medication but the medication name stays the same, then the coder will code this action as a medication that has been *Started*. If a medication was restarted by the provider (if discussed this way in the medical visit), then the coder should code this as *Start*.

Next, for the **Risks Discussed** box, circle whether or not there was a discussion of risks for that asthma control medication. Code 'Yes' (Y) if there was ANY discussion of risks (regardless of who speaks) or 'No' (N) if there is not any discussion of risks for that asthma control medication.

The Side Effects Discussed box is next and code whether or not there was a discussion of the side effects for that asthma control medication. Code this question as 'Yes' (Y) if there was ANY discussion of side effects (regardless of who speaks) during the medical visit for that asthma control medication or 'No' (N) if there was not any discussion of side effects for that asthma control medication. This box can also be coded "N/A" if the medication is a new medication, since children have not experienced any side effects of a medication they have not taken before.

Lastly, the **Benefits Discussed** box is next to code. Code whether or not there was a discussion of benefits for that asthma control medication. Code ‘Yes’ (Y) if there was a discussion of benefits for each asthma control medication discussed and code ‘No’ (N) if there was not a discussion of asthma control medications.

Discussions about Side Effects

Side Effects	Yes	No		
Are side effects discussed?	Y	N		
If yes, for what asthma control medication(s)?	1	2	3	4
If yes, who initiates the discussion?	C	P	D	N/A
Does caregiver or patient state experience of side effects?	C	P	D	N/A

For the first row in this table, code whether or not side effects were discussed during the medical visit. Code ‘Y’ if side effects were discussed during the visit and code ‘N’ if side effects were not discussed during the visit.

For the second row in the above box, code the corresponding number(s) from the first table of the asthma control medications.

For the third row in the above box, code who *started* the discussion about side effects. If there was not a discussion of side effects (‘N’ is coded in the first row) then code ‘N/A.’

For the final row in the above box, code who states that the child is currently or has previously experienced side effects. Code ‘C’ if the *caregiver* states the child has experienced a side effect and code ‘P’ if the *patient* states s/he has experienced a side effect. Code ‘D’ if it is the *provider* that states the child has or is experiencing side effects. Code N/A if side effects were not discussed.

Name of Side Effect Discussed
1 _____
2 _____
3 _____
4 _____
5 _____
6 _____
7 _____
8 _____
9 _____

For each row in the above table, copy EACH question and EACH statement that was made about side effects for all applicable medications. The following table is an actual table from the Principal Investigator's coding of a side effect discussion:

Name of Side Effect Discussed	
1	_ MD: You're so funny. You did great on your spirometry and it's normal. It looks good. Alright, so you're taking your Advair? No problems with that? Doing it in the inhaler with your spacer? _____
2	_____
3	_____
4	_____
5	_____
6	_____
7	_____
8	_____
9	_____

2e. Number of caregiver questions about side effects? _____

2f. Number of caregiver statements about side effects _____

2g. Number of child questions about side effects? _____

2h. Number of child statements about side effects _____

2i. Number of provider questions about side effects? _____

2j. Number of provider statements about side effects _____

For each question above, count and sum each participants' respective questions and statements from the box above and place the answer in the provided space.

Discussions about Risks

Risks	YES	NO		
a. Are risks discussed?	Y	N		
b. If yes, who initiates?	C	P	D	N/A

For the first row in the above box, code whether there is ANY discussion of risks during the medical visit, regardless of who participates in the discussion. Code “Y” (yes) if there is a discussion about risks of an asthma control medication. Code “N” (no) if there is not any discussion about the risks of using an asthma control medication.

For the second row in the above box, code who *started* the conversation about risks. Code “C” if the caregiver starts the discussion, “P” if the child starts the conversation, and “D” if the provider starts the discussion. Code “N/A” if there is not a discussion of risks.

c. Identity of risk discussed	d. Is Permanence Discussed	e. Is Timing Discussed	f. Is Probability Discussed	g. Are Values Discussed	h. Is Severity of Risk Discussed
1	Y N	Y N	Y N	Y N	Y N
	N/A	N/A	N/A	N/A	N/A
2	Y N	Y N	Y N	Y N	Y N
	N/A	N/A	N/A	N/A	N/A
3	Y N	Y N	Y N	Y N	Y N
	N/A	N/A	N/A	N/A	N/A
4	Y N	Y N	Y N	Y N	Y N
	N/A	N/A	N/A	N/A	N/A
5	Y N	Y N	Y N	Y N	Y N
	N/A	N/A	N/A	N/A	N/A
6	Y N	Y N	Y N	Y N	Y N
	N/A	N/A	N/A	N/A	N/A
7	Y N	Y N	Y N	Y N	Y N
	N/A	N/A	N/A	N/A	N/A
8	Y N	Y N	Y N	Y N	Y N
	N/A	N/A	N/A	N/A	N/A
9	Y N	Y N	Y N	Y N	Y N
	N/A	N/A	N/A	N/A	N/A

For each row in the above box, code each asthma control medication risk that is discussed during the visit. Each column from the above table needs to be coded in addition to the name of each risk that is stated. The concepts for each column is defined below:

- **Risk Identity:** The name of the risk. Examples of names of risks are: shorter stature, glaucoma, oral thrush, etc.
- 5.
- **Permanence:** The duration of the risk. The duration of the risk may be temporary (e.g. oral thrush from using an inhaled corticosteroid) or permanent (e.g. shorter adult stature)
 - **Timing:** When the risk is likely to occur.
 - **Probability:** The likelihood of experiencing the risk. This includes quantitative probability discussions, such as 1%, 1 in 1,000 etc. to describe the likelihood of a risk occurring. This dimension also includes qualitative probability discussions that use words such as rare, common, not common, frequent, etc. to describe the likelihood of a risk occurring.
 - **Value:** The caregiver's and/or the child's perception of the importance of the risk for him/herself (how much does the risk matter to the caregiver or child?).
 - **Severity:** The gravity of the risk. Can the risk result in blindness (from glaucoma after using inhaled corticosteroids) or death (as a result of only using a long-acting beta-agonist in treating persistent asthma)?

3i. Does provider discuss probability qualitatively? Y N N/A

3j. Does provider discuss probability numerically? Y N N/A

The above two questions are only applicable IF there is a discussion about the probability of a risk occurring.

Question 3i should be coded "Y" (yes) if there is a discussion about probability that used words (as described above) to communicate the likelihood of a risk occurring and "N" (no) if there is not a discussion that used words to describe the likelihood of a risk occurring. The coder should code "N/A" if there is not any discussion about the probability of a risk occurring.

Question 3j should be coded "Y" (yes) if there is a discussion about probability that used numbers (as described above) to communicate the likelihood of a risk occurring and "N" (no) if there is not a discussion that used numbers to describe the likelihood of a risk occurring. The coder should code "N/A" if there is not any discussion about the probability of a risk occurring.

3k. Number of caregiver questions about risks? _____

3l. Number of caregiver statements about risks _____

3m. Number of child questions about risks? _____

3n. Number of child statements about risks _____

3o. Number of provider questions about risks? _____

3p. Number of provider statements about risks _____

For each question above, count and sum each participant's respective questions and statements about risks and place the answer in the space provided.

Discussions about Benefits

Benefits Discussed	YES	NO		
a. Are benefits discussed	Y	N		
b. If yes, who initiates?	C	P	D	N/A

For the first row in the above box, code whether there was ANY discussion about the benefits of using an asthma control medication, regardless of who speaks in the discussion. Code "Y" (yes) if there is a discussion about benefits of using an asthma control medication and code "N" (no) if there is not a discussion about the benefits of using an asthma control medication.

For the second row in the above box, code the participant that *started* the conversation about the benefits of the asthma control medication. Code "C" if the caregiver started the conversation about benefits, code "P" if the child started the conversation about benefits, and code "D" if the provider started the conversation about benefits. Code "N/A" if there is not a discussion about benefits of using asthma control medications.

c. Names of Benefits Discussed
1 _____
2 _____
3 _____
4 _____
5 _____
6 _____
7 _____
8 _____
9 _____

For each row in the above box, copy and paste *each* question and statement from the transcripts of the medical visit. The following table is an actual table from the Principal Investigator's coding of a benefit discussion:

c. Names of Benefits Discussed
1 _ MD You are so much better than you were. _____
2 MD But it's that medicine, honey, that prevents you from having trouble. _____
3 MD I mean it's that medicine that does it.
4 _____
5 _____
6 _____
7 _____
8 _____
9 _____

4d. Number of provider statements about benefits _____

4e. Number of provider questions about benefits _____

4f. Number of caregiver statements about benefits _____

4g. Number of caregiver questions about benefits _____

4h. Number of patient statements about benefits _____

4i. Number of patient questions about benefits _____

For each question above, count and sum each participant's respective questions and statements about benefits and place the answer in the space provided.

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