Introduction to Revised Application

We appreciate the reviewers' comments regarding the importance of our proposed study. We have substantially modified the proposal to address the important points made by the study section. As a result of the study section's suggestions we believe the proposal has been strengthened considerably. The major concerns raised by the study section, along with our responses are summarized below. **NOTE: Changes in this revised application are identified with vertical lines at the left margin.**

Critique One

1. The conceptual model does not follow clearly from the aims.

We have modified the conceptual model so that it flows more clearly from the aims.

2. The background does not separate the child-provider and caregiver-provider literature.

We did not separate the literature because there are very few studies that examine child-provider and caregiver-provider communication during medical visits. In addition, we believe it flows better to discuss the findings together. However, we have expanded our discussion of prior studies that have examined caregiver-provider communication.

3. The investigators discuss three elements of communication, but it is difficult to be convinced that others are not more important.

We have selected our four main measures of communication (education, modeling/skill development, engagement of the child, engagement of the caregiver) based upon what the NHLBI guidelines state are important areas for providers to cover during asthma visits. Also, these areas are often covered in asthma education programs, so we wanted to examine the extent to which pediatricians discuss these areas in routine practice. However, if other dimensions of communication appear to be important while we are analyzing the audio-tapes, we will be able to look at these other aspects of communication since we will have the audio-tapes and transcripts of the medical visits. We now explain this in Section D.6.c of the proposal.

4. The investigators do not discuss interventions for asthma and other diseases to improve communication or offer support of the notion that a descriptive rather than an interventional study is necessary.

An important goal of this project is to identify best practices for training providers to improve child asthma outcomes. However, an intervention to improve provider-caregiver-child communication may be premature until we have a better understanding of the communication that occurs in pediatric medical office visits, and how this communication is related to child asthma outcomes. We have expanded our discussion of prior asthma management intervention studies in Section B.6 to support this position. We also discuss intervention studies that have been conducted to improve communication in other diseases to point out why a descriptive study is needed prior to designing an intervention trial.

5. The investigators do not appear to have pilot tested the feasibility of home visits.

We have piloted the home visits with six families. The home visits were well-received and not overly burdensome in terms of time. Results of this pilot are now presented in Section C.3 of the proposal.

6. They have not piloted their survey of caregivers.

We have pilot tested both caregiver surveys – after the medical visit and home visit. The caregivers reported no problems in completing the surveys and required approximately 30 minutes to complete them. These pilot results are now presented in Sections C.2 and C.3 of the proposal.

7. The preliminary research section would be strengthened by a more thorough discussion of Dr. Sleath's NIMH-funded project and details of relevant research of the other Key Personnel.

We have included a more thorough discussion of Dr. Sleath's NIMH-funded project and the currently funded NIA grant that UNC is conducting with UW-Madison. In the NIA grant, Dr. Sleath is coordinating data collection at five geographically dispersed NC rheumatology clinics. The experience she and her team are gaining at the rheumatology clinics will provide valuable information about how to work effectively and efficiently with the pediatric clinics. We also have expanded our discussion of other studies conducted by other Key Personnel.

8. The investigators have not addressed the criticism of the previous review that telling the physicians the hypothesis may change behavior.

We are not providing the physicians with the specific study hypotheses. Our IRB consent form simply states the minimum required for obtaining informed consent: "the purpose of this research study is to examine communication during pediatric asthma visits. We will conduct interviews with children and their caregivers about physician visits, as well as to learn about the child's asthma and the effect that it has had on their lives."

9. The reason for the second interview is not clear. There is no motivation for the timing of the second interview one month following their clinic visit.

We have clarified our motivation for the second interview occurring one month after the medical office visit (see Section D.3).

10. The reviewer does not agree that all the children should be drawn from private practices. They may be different from patients who attend public clinics in terms of socio-demographics and disease severity.
We recognize the limitations imposed by recruiting children and caregivers from predominantly private practices. Nevertheless we have attempted to safeguard against selection bias by: a) recruiting one public clinic to participate in this study and b) recruiting private practices serving a diverse population (see Table 2 in Section D.2). In addition, many of the practices serve a low socioeconomic population as evidenced by the number of patients on Medicaid.

11. In Table 2 we are not told how many people have asthma in these practices or their distribution according to severity. Because these are primary care practices, there is concern there will be sufficient patients with moderate and severe asthma.
We now provide information on severity levels in Table 3 and accompanying text in Section D.3.

12. The investigators do not offer support for excluding non-English speaking caretakers, rather than including non-English speakers and providing translators.
We recognize and appreciate this important point to improve the generalizability of our study to those children and families who are not English-language dominant. However, as indicated in Section D.11, we believe that having professional interpreters, or more commonly, older siblings and family members serving as interpreters, will significantly alter the communication that occurs between providers, caregivers, and children.

13. We are not told how many of the Hispanic patients and their caretakers speak English, and thus will be included. We are not assured there will be no selection bias.
Meetings with clinic administrative staff and physicians suggest that close to 50% of Hispanic caregivers will speak English and will be included in the study. We address this in Sections D.3 and D.11.

14. Definition of persistent asthma is not clear, so inclusion is not clear.
The definition has been clarified in Section D.3.

15. It is not clear how stratifying by asthma severity will be operationalized.
We have more clearly explained how we will stratify by asthma severity when sampling patients in Section D.3 and how we will operationalize asthma severity for analysis purposes in Section D.6.d.

16. The "modified asthma severity classification" attempts to take into account asthma control, but it is not a validated measure and rather imprecise.
We no longer propose to use the "modified asthma severity classification" in an attempt to account for asthma control. As shown in Section D.6.d, we now propose to use the NHLBI guidelines plus a validated way to take into account a child's medication use when determining severity (Lewis et al. 2004).

17. The investigators have changed from parent to caretaker in this revision, but caretaker is not defined.
We now define caregiver in the proposal (see Section D.3).

18. The investigators need to provide more detail on the process of recruitment, no-show rates, and how far apart the clinics are from one another.
This information is now more clearly defined in Sections D.2 and D.3 of the proposal, primarily informed by recommendations from administrative staff and physicians at participating clinics.

19. It is not clear if literacy will be a problem for caretakers making it difficult to complete a survey.
We appreciate this concern and have modified our exclusion criteria to exclude caregivers who are unable to read and understand the informed consent form. We realize this is a limitation of the study and discuss our rationale for excluding caregivers who cannot read English in section D.11.

20. The authors do not discuss if measurements will be different depending on the age of the child.
We have pilot tested our child interviews and have found them to be understood by children whose ages meet our inclusion criteria. Thus, we do not propose using different measurement instruments based on the child's age.

21. The investigators do not discuss if there will be stratification by age.
We believe it is more important to stratify by asthma severity. However, we will adjust for age in all of our analyses.

22. The investigators state if the child does not bring in their medication, the caretaker will be given the MDILog to place on the patient's medication at home. That will very likely be difficult for caretakers if not impossible.
We will show the caregivers how to place the MDILog on medication similar to the patient's during the first interview in the medical office setting and we will call them to make sure the caregivers successfully completed this task. If the caregiver is unable to get the MDILog on the patient's medication then the research assistant will travel to the patient's home to place it on the medication for the patient.

23. The investigators do not discuss how they will handle the incongruencies of measures (if caregiver and child disagree).
If we have duplicate child and caregiver measures (e.g. ER visits) we will use the caregiver measures in our analysis given the age range in our proposed sample. We feel more confident using caregiver-reported data for some of the less

subjective primary and secondary outcomes, specifically medication adherence, environmental trigger control, school absences, ER visits, and unscheduled physician visits. However, because the primary hypothesis involves examining child asthma outcomes, all other primary and secondary outcome analyses will use child-reported, measured, and/or observed data: inhaler and peak flow technique; satisfaction with visit; self-efficacy, outcome expectations, lung function, asthma symptom days, and quality of life. Additionally, since we will have both caregiver and child measures, we can examine if there are incongruencies.

24. It is not clear how long the interview will be and if the amount of time is burdensome to patient and caregiver and will burden be different for children of different ages.

We now present pilot data on the length of the child interviews and the caregiver surveys in Section C.3.

25. We do not examine whether children can use a peak flow meter.

We acknowledge the importance of this research question and now propose to examine the child's ability to use a peak flow meter. Given the lack of published data on this topic (Scarfone et al., 2002), this research question has become a primary aim along with how well the child is able to use a metered-dose inhaler.

26. Investigators do not explain how they will separate in the analysis information addressed during the visit versus information the patient remembered from the visit.

We understand the importance of examining what patients remember but if we ask patients detailed information about what the physician did and did not communicate to them after the visit to assess what they remember then this could potentially influence their behavior and outcomes one month later. Although this is a good idea, it would fit better in a different study.

27. The investigators might consider piloting the self-report environmental control measure and having a more objective measure.

We will now use a self-report environmental control measure that has been validated. Dr. Ayala has used this self-report measure before during her involvement with the PAC-PORT study and we have pilot tested it in home visit interviews. We will also now use an objective measure of environmental control that has been developed by the North Carolina Department of Health and Human Services. Both measures are discussed in Section D.6.b. We have pilot tested both instruments in our home visit interviews.

28. There is no discussion as to why locus of control is important.

We have decided to delete the locus of control measure since the psychometric properties of the scale are less than adequate and the construct is no longer a good fit with the revised conceptual model.

29. The investigators state they will collect information on affective response to asthma and on caregiver expectations, but there is no description of this data.

We now describe these measures in Section D.6.d.

30. The validity of 0.28 as a clinically important effect size is not well documented.

We have modified Section D.8 accordingly to address the reviewer's concerns.

31. The investigators assume a 10% attrition rate but give no support for this estimate.

Prior studies of pediatric asthma that have followed families for a year reported attrition rates ranging between 18 and 21 percent (Krieger et al. 2002; Sharek et al. 2002). Since we are only following families for one month we expect an attrition rate of only 10 percent.

Critique Two

1. It is not clear whether participants will be consecutively enrolled or whether each practice will rotate in entering individuals into the investigation.

There will be a 36-month enrollment period. We intend to enroll patients at four clinics for the first 18 months of the enrollment period and at four different clinics for the last 18 months of the enrollment period. Each clinic will receive $500 a month for each month that they enroll patients into the study.

2. It is unclear how school absences will actually be assessed.

We will assess school absences for the past 2 weeks on the caregiver survey. Consistent with methods used in previous studies, caregivers will be given a two-week calendar and asked to identify all important events that transpired during that two-week period. The caregiver is then asked to identify what days the child missed school during the same two-week period. This protocol assists with recall of more typical events in the context of atypical events during the same time period. School absences have been assessed through self-report in prior studies which are cited in Section D.6.b.

3. The applicants propose to measure number of ER visits in the past month but is this possible with HIPAA requirements.

We will be measuring ER visits by caregiver self-report, which has been done in previous studies as cited in Section D.6.b.

A. Specific Aims

The project is focused on a neglected area within children's health services research, the relationship between provider-child-caregiver communication during pediatric asthma visits and treatment adherence. Treatment adherence comprises medication adherence, symptom monitoring, and environmental trigger control. Thirty-five physicians and their nurses and 360 English-speaking child-caregiver pairs will be recruited at eight pediatric clinics. Children will be eligible if they are between 8 and 15 years of age, have mild, moderate, or severe persistent asthma, and have previously visited the clinic at least once before for asthma. Caregivers will be eligible if they are at least 18 years of age and are the biological parent or legal guardian of the child with asthma. Determination of inclusion criteria (age, asthma severity, and physician visit) are based on administration of a screener prior to the informed consent process. Consent and assent to participate will be obtained from the caregivers and children respectively. Physicians and nurses will fill out a demographic questionnaire at the start of the study. The children will have their health care provider visits audio-tape recorded. The children will be interviewed after their medical visits and asked to demonstrate inhaler and peak flow technique. They also will receive a lung function test using spirometry. The children's caregivers will fill out questionnaires after these visits. A home visit will occur one month after the audio-taped visit during which the child will participate in an interview and receive a second lung function test. The caregivers will fill out a questionnaire and an environmental trigger home inspection will be conducted. Generalized estimating equations will be used to examine how physician and nurse communication about asthma management, modeling of asthma care behaviors, and engagement of the child and caregiver during medical visits, are related to treatment adherence.

The primary aims of the project are:

1. To examine how physician and nurse communication about asthma management, modeling of asthma care behaviors, and engagement of the child and caregiver during pediatric asthma visits are related to medication adherence.
2. To investigate how physician and nurse communication about asthma management, modeling, and engagement of the child and caregiver during pediatric asthma visits, are related to observed performance of inhaler and peak flow technique.
3. To investigate how physician and nurse communication about asthma management, modeling, and engagement of the child and caregiver during pediatric asthma visits, are related to caregiver and child satisfaction with the visit.

The secondary aims of the project are:

4. To examine how physician and nurse communication about asthma management, modeling of asthma care behaviors, and engagement of the child and caregiver during pediatric asthma visits are related to symptom monitoring and environmental trigger control.
5. To examine how physician and nurse communication about asthma management, modeling, and engagement of the child and caregiver, are related to child and caregiver self-efficacy and outcome expectations.
6. To describe how physician and nurse communication about asthma management, modeling, and engagement of the child and caregiver, are related to child and caregiver quality-of-life.
7. To describe how physician and nurse communication about asthma management, modeling, and engagement of the child and caregiver, are related to (a) lung function, (b) school absences, (c) emergency room visits, (d) unscheduled physician visits, and (e) asthma symptom days.

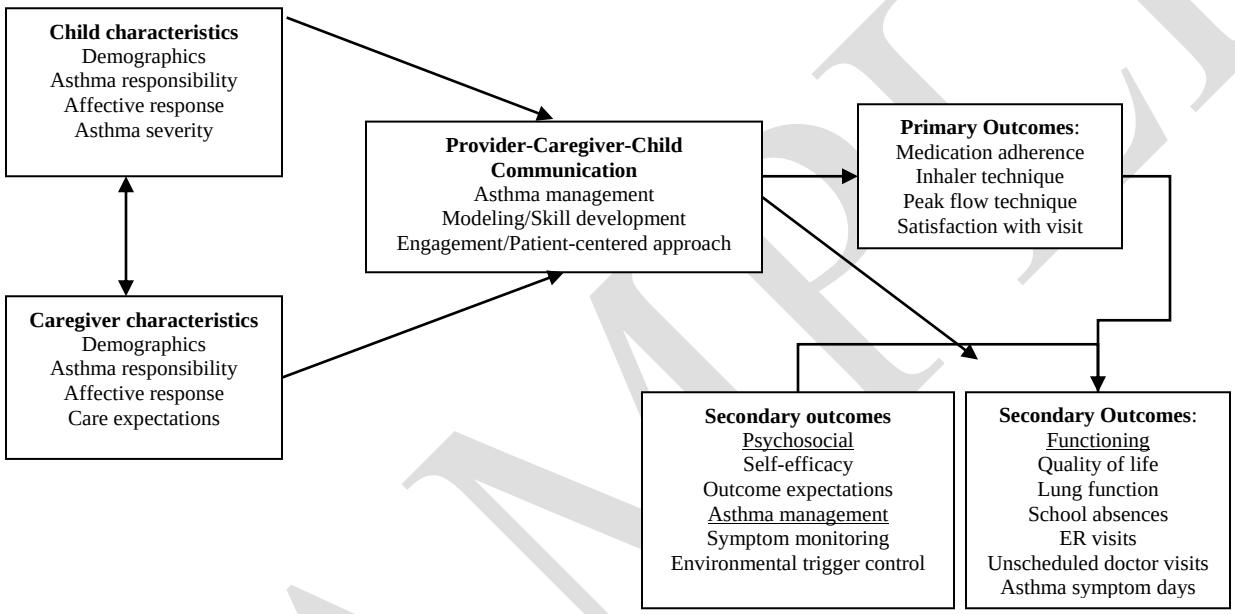
B. Background

Asthma is the most common chronic condition among U.S. children (Adams et al. 1995). It is the ideal disease to examine provider-child-caregiver communication about disease management. There are more than 4.8 million children under age 18 in the United States with asthma (Adams et al. 1995). Healthcare costs for asthma are estimated at more than 6 billion dollars a year and loss in productivity by working parents caring for children who miss school due to asthma is estimated at one billion dollars a year (NHLBI, 1997; NIH, 2002).

It is important to examine provider-child-caregiver communication about asthma. Asthma patients who reported poor communication with their physicians were found to be less adherent with inhaled steroids taken twice daily (Apter et al. 1998). Part of the asthma management program presented in the Global Strategy for Asthma Management and Prevention NHLBI/WHO Workshop Report (1995) emphasizes that in the physician-patient relationship there is a need to: (a) educate patients to develop a partnership in asthma management and (b) establish individual medication plans for long-

term management. The clinical practice guidelines of the National Asthma Education and Prevention Program of NHLBI reemphasize these points (NHLBI, 1997; NIH, 2002). The clinical guidelines also encourage physicians to discuss the following with patients at every follow-up asthma visit: the expectations of the visit, the goals of treatment, medications, and quality-of-life (NHLBI, 1997; NIH, 2002). They also emphasize the importance of jointly determining the goals of treatment with the patient and family (NHLBI, 1997). Therefore, the purpose of this application is to examine how physician and nurse communication about asthma management, modeling, and engagement of the child and caregiver, are related to treatment adherence, inhaler and peak flow technique, satisfaction with medical visit, child and caregiver self-efficacy and outcome expectations, quality-of-life, and functional status (e.g. lung function, school absences). Figure 1 presents the theoretical framework for our application, which is based upon Social Cognitive Theory (Bandura, 1986). We will now turn to a discussion of each of the following components of our theoretical framework: (a) provider-child-caregiver communication (asthma management education, modeling/skill development, engagement/child-centered approach), (b) self-efficacy and outcome expectations, (c) satisfaction, (d) treatment adherence, and (e) child and caregiver outcomes.

Figure 1: Theoretical Framework Based on Social Cognitive Theory



B.1 Provider-child-caregiver interaction

We conceptualize that there are three important components of provider-child-caregiver communication during pediatric asthma visits. The first is the extent to which the provider educates the child and caregiver about asthma management. The second is the extent to which the provider uses modeling and skill development to help children learn how to appropriately manage their asthma. The third is the extent to which the provider engages the child and caregiver during the visit (e.g., uses a child-centered and caregiver-centered approach).

B.1a Asthma management education

Little is known about the extent to which providers educate children and their caregivers about asthma during pediatric visits. Clark et al. (1997) developed an excellent physician self-report scale for assessing health care providers' teaching and communication behavior regarding asthma that was validated by patient reports of provider behavior. The scale assesses how well physicians focus on the treatment plan, provide a congenial demeanor and reassuring communication. However, it does not specifically address how often physicians direct this behavior at caregivers versus children. Clark et al. (2000; 1998) then conducted a physician education randomized clinical trial. The researchers found that physicians in the intervention group were more likely than control group physicians to address patients' fears about medicines, review written instructions, provide a sequence of educational messages, and write down how to adjust the medicines at home when symptoms change according to caregiver and physician self-report. They did not examine differences in communication to children and caregivers in this study. This was an important study, yet new knowledge could be gained

by actually examining the extent to which providers educate children and caregivers about asthma during audio-taped medical visits.

There is evidence that caregivers and children want and need to learn more about asthma management. Haby et al. (2002) found that 51 percent of caregivers felt they did not have enough information about asthma triggers, more than 60 percent of children with persistent or frequent episodic asthma were not using regular preventive medication, and 48 percent did not have a written action plan. Warman et al. (1999) found that only 39 percent of the children in their sample with persistent symptoms were receiving daily anti-inflammatory agents as recommended in the NHLBI guidelines and only 30 percent of families with children age 5 years and older had peak flow meters.

There is also evidence that exposure of children with asthma to potential environmental triggers is common. Finkelstein et al. (2002) found that 30 percent of households with a child with asthma had a smoker, 18 percent had household pests, and 59 percent had furry pets. They also found that most children did not have mattress (65%) or pillow covers (84%) (Finkelstein et al. 2002).

There is increasing national attention on the role of children in medication-taking and self management of chronic diseases. In 1996, the United States Pharmacopoeia (USP), a national organization that sets official standards for drug purity, sponsored an open conference on the need and rationale for teaching children and adolescents about medicines. After the conference, the USP adapted a position statement, "Ten Guiding Principles for Teaching Children and Adolescents about Medicines" which supports the rights of children and adolescents to receive developmentally appropriate information and direct communications about medicines (Bush et al, 1999). Four of these ten guiding principles relate and can be applied to provider-caregiver-child communication about asthma management. They are:

(1) Children want to know. Health care providers and health educators should communicate directly with children about medicines.
(2) Children's interest should be encouraged, and they should be taught how to ask questions of health care providers, parents, and other caregivers about medicines and other therapies.
(3) Children, their parents, and their health care providers should negotiate the gradual transfer of responsibility for medication use in ways that respect caregiver responsibilities and the health status and capabilities of the child.
(4) Children's medication education should take into account what children want to know about medicines, as well as what health care professionals think children should know.

Eggleston et al. (1998) found that more than half of the asthmatic children $\geq$ 9 years supervised their own medication, which suggests that providers and caregivers are often transferring the responsibility of asthma management over to children, without necessarily a concurrent transfer of asthma management education directed to the child's developmental stage.

B.1.b Modeling/skill development
Modeling and skill development are critical components of Social Cognitive Theory (Bandura, 1986; Barnowski et al. 2002). Nader (1985) and Elder, Ayala, and Harris (2000) suggest that physicians can apply Social Cognitive Theory techniques and model for the caregiver how to give the child more decision-making in his/her care. Providers can also model the use of inhalers and peak flow meters during asthma visits to improve asthma management among children and their caregivers. Providers can then have children demonstrate how to use inhalers and peak flow meters during medical visits to help develop their self-efficacy and use of these devices. To our knowledge, no prior study has examined the extent to which providers model asthma management behaviors and attempt to develop children's asthma management skills during pediatric asthma visits.

B.1.c Engagement/child-centered or caregiver-centered approach
Physicians use various styles when interacting with patients. From a theoretical perspective, two of the most commonly referenced styles are: (1) a paternalistic style where the physician dominates and controls the decisions made during an encounter, and (2) a participatory or patient-centered style where both the physician and patient are involved in making treatment decisions (Roter & Hall, 1992). Clark et al. (1995) found that adult patients with asthma expressed a desire for a relationship with the provider that involved mutual respect and a sense of partnership. Adams et al. (2001) found that adult patients with asthma who rated their physicians as being more participatory had a significantly better health-related

quality of life. Chambers et al. (1999) found that adult patients with asthma were more likely to report regular use of inhaled corticosteroids, if they saw themselves as active participants in their treatment planning. We are interested in examining the extent to which providers used a child-centered and a caregiver-centered approach during the visit and how this is associated with child and caregiver-reported quality-of-life.

Previous work examining pediatric visits has found that physicians tend to involve children more when gathering information during the visit but much less so in discussions of treatment options (Pantell et al. 1982; Stewart et al. 1981). Wissow et al. (1998) examined physician-caregiver-child communication about all aspects of asthma care during emergency visits and found that children seldom took part in discussions. The researchers also found that provider use of a patient-centered style with children was associated with five times the amount of talk from children and with higher parent ratings for "good care". Wissow et al. (1998), in their study of communication during emergency department care of children with asthma, found that provider use of a patient-centered style with parents was associated with more talk with parents and higher ratings for informativeness and partnership. To our knowledge, no prior work has examined provider-caregiver-child communication during asthma visits in pediatric practices and how this impacts the amount of talk, quality of care, and patient outcomes.

Lewis et al. (1991) conducted a brief educational intervention to promote effective communication among physicians, children, and parents during pediatric office visits. They performed a randomized clinical trial involving 141 children age 5 through 15 years and found that physicians in the intervention group included children more in discussions of medical recommendations and that children recalled more medication recommendations, reported greater satisfaction with the visit, and a greater preference for an active role in health care. Their study, however, did not examine how the educational intervention impacted physician-caregiver communication. In addition, the study did not focus on asthma and it did not examine quality-of-life. There is a need to examine how often physicians involve children and their caregivers in asthma management decisions during medical visits and how this influences treatment adherence, inhaler and peak flow technique, satisfaction, quality-of-life, and other outcomes.

It is also important to determine what demographic factors (age, race, gender) are related to child and caregiver involvement in asthma management discussions during medical visits. This information may help us better understand how to socialize children and their caregivers to become more actively involved in discussing asthma management with their providers. The skills needed for effective asthma management are unique and support greater child involvement. Studies have found that patients are more adherent to medical regimens and have better outcomes after medical visits where they have perceived themselves as being more actively involved (Kelly & Scott, 1990; Roter, 1977).

B.2 Self-efficacy and outcome expectations

Bonner et al. (2002) conducted an intervention study to improve asthma management among urban Latino and African-American families. A family coordinator provided patient education and facilitated interactions between families and physicians by coaching families to provide detailed asthma histories to their providers. The results indicated significant improvements in self-efficacy and adherence, and a decrease in symptom persistence and activity restriction. Clark et al. (1988) found a modest relationship between child self-efficacy and asthma self-management, but they comment that it may have been because they only used one general item to measure self-efficacy. More recently, Bursch et al. (1999) have developed reliable and valid child and caregiver asthma self-management scales that include a measure of self-efficacy and found that they correlate strongly with health status, asthma symptoms, and impact of illness on the family.

B.3 Satisfaction

Lewis et al. (1991) found that children were more satisfied with their medical visits when physicians included them more in discussions of medical recommendations. Wissow et al. (1998) found that if emergency room physicians used more patient-centered styles with children with asthma, parents rated the physicians higher on providing "good care". Smith et al. (1987) found that asthmatic children who had parents who were more satisfied with the asthma care they received were more adherent to their asthma medications. Parent satisfaction was related to current medication adherence as well as future asthma medication adherence (Smith et al. 1987). These prior research findings suggest the importance of examining caregiver and child satisfaction with asthma visits and how satisfaction is related to asthma treatment adherence.

B.4 Treatment adherence

Treatment adherence is an important component of asthma care. Warman et al. (1999) found that only 39 percent of children with persistent symptoms were receiving daily anti-inflammatory agents as recommended by the NHLBI guidelines. Similarly, Haby et al. (2002) found that 60 percent of children with persistent or frequent asthma were not using regular preventive medicine. Smith et al. (1986) found that good medication compliance was related to perceiving the physician as being interested and approachable and one who gave clear and adequate information. LeBaron et al. (1985) found that an educational program to improve compliance with cromolyn among children and adolescents resulted in improved adherence and health status only if the quality of management by the physician was taken into account. Apter et al. (1998) found that poor patient ratings of patient-provider communication about asthma were related to poor adherence to inhaled steroids. Chambers et al. (1999) discovered that regular inhaled corticosteroid use was related to whether patients perceived themselves as actively involved in treatment decisions during medical visits. This prior research suggests that better provider education of children and caregivers and better engagement of the children and caregivers during medical visits might improve child adherence to asthma medication and other outcomes.

Many studies have found that asthma symptoms are exacerbated with exposure to environmental triggers (Krieger et al. 2002; Wamboldt et al. 2002). Wamboldt et al. (2002) found that household exposure to environmental tobacco smoke and pets among children with asthma was comparable to normal levels in the U.S. population. Jones et al. (2001) conducted an asthma education program for 204 underserved Latino families with an asthmatic child and found that families who made significant changes to the child's bedroom environment decreased the number of triggers that children were exposed to. To our knowledge no prior study has examined provider-caregiver-child communication about environmental control and avoidance of triggers and how this is related to environmental control and trigger avoidance in the homes of children with asthma.

B.5 Child and caregiver outcomes

Williams et al. (2000) found a significant correlation between child and caregiver quality-of-life and the number of school days the child missed. Clark et al. (2000) found that children seen by physicians who had been through an asthma educational intervention program had fewer hospitalizations than children seen by physicians who did not get the intervention. It is important to better understand how physician and nurse communication about asthma management, modeling, and engagement of the child and caregiver, are related to: (a) quality of life, (b) school absences, (c) emergency room visits, (d) unscheduled physician visits, and (e) asthma symptom days.

B.6 Prior asthma intervention studies and the need for a descriptive provider-caregiver-child communication study

There have been several successful asthma intervention studies conducted whereby caregivers and children are taught, outside of pediatric visits, about how to manage the child's asthma (Bonner et al. 2002; Clark et al. 2000,1998,1986; Tieffenberg et al. 2000). For example, Bonner et al. (2002) conducted an intervention study to improve asthma management among urban Latino and African-American families. A family coordinator provided patient education and facilitated interactions between families and physicians by coaching families to provide detailed asthma histories to their providers. The results indicated significant improvements in self-efficacy and adherence, and a decrease in symptom persistence and activity restriction. The study did not examine how the intervention impacted provider-patient communication. Similarly, Clark et al. (1998;2000) used a randomized controlled trial (RCT) design and assigned physicians to a control group or program group to examine the effects of an interactive seminar on 74 pediatricians and 637 of their patients with asthma. Physicians in the program group were assisted to observe, evaluate, and react to their own efforts to treat and educate their patients according to the theory of self-regulation. The interactive seminar had significant impact on prescribing and communications behavior of physicians, led to more positive patient responses to physicians' actions, and led to reductions in health care utilization. The major limitation of this study is that it relied on physician self-report of their behavior during pediatric visits and parent reports of physician behavior during pediatric visits. It did not actually examine how physicians educated children and their caregivers. There is a need to understand what specific physician behaviors during pediatric asthma visits are related to better outcomes.

In a different intervention study, Clark et al. (1986) evaluated the impact of a health education program to improve family management of asthma. Three hundred and ten children with asthma and their 290 parents were randomly assigned to a program or control group. Educational sessions focusing on how to manage asthma and how to get information from your doctor were held weekly in the clinics. During five sessions parents and children met separately and in one they met together. Following education, program parents scored better on an asthma self-management index and they reported

more use of guidelines to determine physical activity of children. Also program children reported more use of management steps such as breathing and relaxation exercises and less worry than control children. Tieffenberg et al. 2000 conducted a RCT of 355 children with moderate to severe asthma or epilepsy. Families assigned to the experimental group had five meetings with educators (children in one group and parents in another) who trained children to assume a leading role in their care and parents learned to be facilitators. Parents in the experimental group were more likely to report that their relationships with their physicians had improved than parents in the control group and asthmatic children had fewer crises than controls after the intervention and fewer visits to their physicians.

The above intervention studies were effective, but they are often difficult to implement in real life, because they are costly to implement and they take up additional caregiver and child time. If we could better understand the communication process during pediatric visits and how this is associated with child outcomes, then we could design an intervention study to improve communication during pediatric visits that could be readily adapted into practice.

B.7 Summary and rationale for project

In summary, there is a need to better understand provider-caregiver-child communication about asthma during pediatric visits and how this impacts treatment adherence, inhaler and peak flow technique, and satisfaction as well as other outcomes. This will be one of the first studies to examine the extent to which providers educate and involve children and caregivers in asthma management decisions, which the NHLBI guidelines suggest that providers should do this at every visit (NHLBI, 1997; NIH, 2002). The findings from this study can be used to educate providers, caregivers, and children about how to optimize communication during pediatric asthma visits to assure improved child and caregiver outcomes. If we find that provider communication about asthma management, modeling, and engagement of the child and caregiver during medical visits is related to treatment adherence and other outcomes, we can then design intervention studies to improve communication between children, caregivers, and providers during pediatric asthma visits.

C. Preliminary Studies

The research team has conducted a variety of previous studies that are relevant to this project. In this section, we will describe these experiences and provide background on two pilot studies we conducted, one where we pilot tested audio-taping visits, interviewed the child and had the caregiver fill out a questionnaire after the visit and one where we pilot tested the home data collection visits with the children and caregivers.

C.1 Research Team

Dr. Betsy Sleath has gained extensive experience in the collection, transcription, measurement, and analysis of data on physician-patient communication about medications in primary care settings (Sleath et al. 2003; Sleath et al. 2002; Sleath et al. 2001; Sleath et al. 2000; Sleath et al. 1999; Sleath et al. 1998; Sleath et al. 1997). Her work in this area has been funded by NIA, NIMH, AHRQ, and the Bayer Institute for Health Communication. Dr. Sleath supervised the collection of 427 audio-tapes of physician-patient encounters at the University of New Mexico Health Sciences Center's family practice and general medicine clinics during 1995. Both English and Spanish-speaking patients were recruited. Clinic staff referred eligible patients to research assistants who were in the waiting areas of the clinics when participating physician had clinic. Eighty percent of approached patients participated in the study. Dr. Sleath received a FIRST award from NIMH to use this same data set to examine the influence of patient gender, ethnicity, and language on physician-patient communication about mental health care issues in primary care settings. Dr. Sleath and her team developed reliable coding tools in the NIMH funded project to examine communication about depression and antidepressant medications (Sleath et al. 2003; Sleath et al. 2002; Sleath et al. 2001). Inter-coder reliability for the coding tools was 0.80 or better for the measures examined in the NIMH funded study which included: physician and patient information giving and question asking about antidepressants; patient expression of complaints and adherence problems with antidepressants; discussion of depression; physician and patient question asking about depression; and counseling during visits.

Dr. Sleath is currently co-principal investigator and site principal investigator on a 2 million dollar grant from the National Institute of Aging. The University of Wisconsin and University of North Carolina received funds to conduct a randomized trial to improve rheumatologist-patient communication about the management of rheumatoid arthritis. Dr. Sleath and her research team are coordinating data collection at five geographically dispersed rheumatology clinics in North Carolina. Some clinics are 2 hours away from UNC. Over 1800 audio-tapes of medical visits are being collected in the study and Dr. Sleath is responsible for coding and analyzing the audio-tape data. The project has hired research

assistants who live near the participating clinics. The clinic staff lets the research assistant know when eligible patients will come to clinic. There are some no-shows (about 20%), but this is expected with this type of research. The research assistant then goes to the clinic and the clinic receptionist refers eligible patients to the research assistants. The research assistant explains the study and obtains informed consent. Approximately 80 percent of eligible patients are participating. The UNC project staff travels to meet with the remote research staff at least monthly. The data collection process is working well and similar techniques will be used in the proposed study. Dr. Sleath also has done prior work in asthma. While at the University of New Mexico, she conducted an educational intervention with physicians and pharmacists who were caring for Medicaid patients who were over-utilizing their $beta_2$-agonist inhalers. The physicians and pharmacists were mailed the NHLBI asthma guidelines and patient profiles. The study found that appropriate use of asthma medications improved if both physicians and pharmacists received the educational intervention (Sleath et al. 1997). Additionally, Dr. Sleath has two recent publications on communicating with children about medications (Sleath, Bush, Pradel, 2003; Sleath and Bush, 2002) and two other papers resulting from work conducted in pediatric settings (Honeycutt and Sleath, 2004; Wurst, Sleath, and Konrad, 2003).

Guadalupe X. Ayala, PhD, MPH is an Assistant Professor in the School of Public Health, Department of Health Behavior and Health Education. Dr. Ayala has experience conducting asthma-related research, primarily in developing culturally and linguistically-appropriate interventions for children and adolescents with asthma. In collaboration with colleagues at the University of Washington, Dr. Ayala developed and implemented a multi-phase intervention for inner-city African-American and Caucasian adolescents with asthma. The intervention included outreach efforts, brief lunch-time educational sessions, and small group discussions on managing asthma at home, at school, and in the doctor's office (NIMH, 2001-2002). She recently received funding from the American Lung Association to develop an asthma management intervention for middle school students and their support network (ALA, 2004-2006). She has completed over 40 focus groups with youth in 6th, 7th, and 8th grade, and interviews with over 10 caregivers and school personnel. A key finding of the youth focus groups was a request for instruction on how to interact more effectively with health care providers. Dr. Ayala found that caregivers and other adults are assuming youth are taking more responsibility for their asthma care, yet the youth report few to no opportunities to discuss asthma management with their health care providers. In addition to these projects, Dr. Ayala is first author on a paper examining psychosocial predictors of childhood asthma medication adherence using data from the multi-site PAC-PORT II study (Ayala, Lozano, Weiss, et al., under review), and she is collaborating with Dr. Yeatts on a manuscript examining predictors of asthma management self-efficacy among middle school students who completed the North Carolina Asthma School Survey. Dr. Ayala research indicates a need for more research and information about how to involve caregivers and health care providers in improving asthma management among children. Her expertise in childhood asthma research will be instrumental in the conduct of this research project, and in particular determining appropriate intervention strategies based on our research findings.

Karin B. Yeatts, PhD, is a Research Assistant Professor in the Department of Epidemiology and in the UNC Center for Environmental Medicine, Asthma and Lung Biology, School of Medicine. She has considerable experience designing and conducting asthma-related research. In collaboration with the North Carolina's Department of Health and Human Services, she surveyed more than 128,000 public middle school students in 1999-2000. She recently conducted a CDC-funded study evaluating asthma-related school absences. Dr. Yeatts has published several papers on the prevalence of diagnosed asthma and undiagnosed wheezing and their health consequences (Yeatts, a,b,c 2003; Yeatts, 2001; Yeatts a,b,c, 2000). She is currently conducting two panel studies evaluating the effects of air pollution on inflammatory markers in children and adults with asthma.

Stephanie Davis, MD is a board certified pediatric pulmonologist on the faculty at the University of North Carolina at Chapel Hill. Dr. Davis' research interests primarily relate to evaluating outcome measures in infants and preschoolers with respiratory illnesses. She has extensive training and expertise in the conduct of infant pulmonary function testing. She recently completed a CFF (Cystic Fibrosis Foundation) Harry Shwachman Clinical Investigator Award to examine the association between infant lung function measurements and bronchoalveolar lavage fluid inflammatory markers in infants with CF and currently has a CFF Clinical Research Grant examining early, reversible CF Lung Disease on HRCT (DAVIS02AO). She is Co-Principal Investigator on the CFF-funded 10-center investigation of lung function testing from raised lung volumes as an outcome measure for clinical trials in infants with CF (ROSENF03AO). She reviews all the lung function data for this large 10 center study and directs the quality assurance of the collected data. Preliminary data revealed that research quality maneuvers (N: 80 studies) were obtained in the majority of the techniques. For the most difficult maneuver, the flow-volume curve, 79% of the curves were research quality. It was concluded that by implementing strict training protocols and a standard operating procedure, infant lung function measures, including

fractional lung volumes and the full flow-volume technique, are feasible in the multi-center setting. Dr. Davis' background in assuring quality assurance for the complicated infant lung function technique will be essential for the spirometric measures obtained for this grant. In addition, she is serving as Co-Principal Investigator for another recently funded CFF Clinical Research Grant entitled "Spirometry as an Outcome Measure in Preschool Children with CF". This study is an eight center study evaluating various lung function techniques as potential outcome measures in both healthy children and children with CF. She also serves as the USA Co-Chair for the ATS Working Group on Infant and Young Children Pulmonary Function Testing and is Associate Director of the Pulmonary Function Laboratory at UNC.

William Campbell, PhD, MS, is Professor of the University of North Carolina School of Pharmacy, and Principal Investigator of the UNC Center for Education and Research in Therapeutics (CERTs). One of seven CERTs funded in 1999 by AHRQ, the UNC program is focused on "Rational Therapeutics for the Pediatric Population" and represents 16 separate research projects conducted in concert with nine public or private partners (e.g., District of Columbia Children's Hospital, United States Pharmacopoeia, Food and Drug Administration, etc.). The mission of CERTs is to stimulate education and research projects that have immediate applications to improving health care. The UNC CERTs research portfolio includes adverse drug event monitoring in acute care settings, active surveillance of adverse events in emergency departments and evaluation and prescribing practices in ADHD. This proposal to study child-caregiver-provider communication about asthma management and child outcomes is synergistic with the mission and goals of the UNC CERTs program. The infrastructure of people and facilities already in place through CERTs will be available to support Dr. Sleath and her colleagues. In addition, Dr. Campbell will serve as a co-investigator on this project to assist in research design, data collection and analysis efforts. Drs. Sleath and Campbell have worked together before on physician-patient communication projects (Sleath et al. 2001a; Sleath et al. 2001b).

Dennis Williams, PharmD has focused his clinical practice and research activities in the area of asthma for the past 10 years. He maintains an active practice with inpatients and outpatients at the university hospital. Dr. Williams represents the American Pharmaceutical Association on the National Asthma and Prevention Program Coordinating Committee and has participated as a faculty member in numerous educational and scientific programs related to asthma management. He has been active in developing and directing several certificate-training programs for pharmacists and respiratory therapists, and is an active member of the Orange County Asthma Coalition in Chapel Hill. He has published numerous articles and chapters on medication use in asthma and helped validate an instrument used to evaluate patients' meter dose inhaler technique (Gray et al. 1994).

Gail Tudor, Ph.D. is Assistant Clinical Professor of Biostatistics at the UNC School of Public Health and an Adjunct Assistant Research Professor at the Duke Clinical Research Institute at Duke University. She is also Assistant Director of the UNC Biostatistics Consulting Laboratory, a recharge center within the Department of Biostatistics of the University of North Carolina at Chapel Hill, which provides biostatistical consultation and data analysis services to investigators within the Health Affairs Division. Dr. Tudor has 15 years of experience in providing statistical consultation for biomedical investigators. She is experienced in the areas of longitudinal data collection and analysis of both categorical and continuous variables.

C.2 Pilot Study on Communication about Asthma in Pediatric Settings

In order to develop our coding tool for the audio-tapes and pretest our interview instruments, we collected pilot data at the University of North Carolina pediatric clinic and a private pediatric clinic. Five physicians participated in the pilot study. Four of the physicians were male and one was African American. One of the physicians had his nurse also do asthma education. When both a physician and then nurse saw a child, both providers' visits were audio-tape recorded and their communication behaviors were summed into an overall provider communication score.

We audio-taped the visits of twelve children (ages 6-15) with asthma and their caregivers who saw one of these five physicians. Fifty percent of the children were female and 33 percent were African American. All of the caregivers were the mothers of the children. We interviewed the children after their visits and the caregivers filled out a survey. All of the audio-tapes were transcribed into text and identifiers were removed. Appendix A contains a sample transcript and the draft coding rules. We examined the following aspects of provider-child-caregiver communication: asthma management communication, modeling/skill development of asthma care behaviors, engagement of the child during the medical visit/child-centeredness, and engagement of the caregiver during the medical visit/caregiver-centeredness. We will briefly discuss the findings below. Table 1 presents a summary of the results.

Asthma management education

We examined two aspects of asthma management education: education about environmental trigger control and education about medications, spacers, and peak flow. We found that during a typical visit providers gave an average of 6.2 different areas of information about environmental trigger control (range 3-12). They were most likely to educate about exercise (75%), allergies/pollen (67%), smoke/smokers (67%), weather (67%), and carpeting (58%). Pets were discussed during 50 percent of visits. Providers were least likely to discuss: heating systems (33%), mattress covers (17%), bedding (17%), plush toys (8%), and fireplaces/wood stoves (none). Inter-rater reliability on environmental trigger control education across two coders was 0.96.

We found that during a typical visit, providers gave an average of 13.7 different areas of information about medications, spacers, and peak flow (range 3-27). Inter-rater reliability across two coders was 0.90. In terms of medications, they were most likely to give information about: amount/dosing (100%), frequency of use (100%), supply of medication (88%), and spacer use (75%). They were least likely to give information about: route of administration (42%) and side effects (33%). Providers gave information about peak flow meters during 50% of visits. They explained how to use peak flow meters during 42% of the visits and they provided a written action plan during 42% of the visits. Providers explained what to do in the different zones during 33% of visits.

Modeling/skill development of asthma care behaviors

Through examination of the transcripts, we determined whether providers demonstrated how to use inhalers, spacers, and peak flow meters and whether providers asked the children to demonstrate how they use their inhalers, spacers, and peak flow meters during the encounters. Inter-rater reliability was 0.96. Only one provider at one visit demonstrated how to use spacers and inhalers. None of the providers demonstrated how to use peak flow meters. However, providers did ask the children to demonstrate how to use the inhaler during 22% of encounters, how to use spacers during 22% of encounters, and how to use peak flow meters during 44% of encounters.

Engagement of the child during the visit/child centeredness

Providers asked children an average of 6.5 questions during a medical visit (range 0-22). Inter-rater reliability was 0.86. They included child input into the asthma management regimen during 33% of the visits. Providers were least likely to ask children questions about medications. They were most likely to ask about peak flow use (42%) and if the child had a written action plan (33%).

Engagement of the caregiver during the visit/caregiver centeredness

Providers asked the caregivers an average of 9.4 questions during a medical visit (range 0-30). Inter-rater reliability was 0.88. They included caregiver input into the asthma management regimen during 33% of the visits. Providers were most likely to ask caregivers about medications. They were least likely to ask caregivers questions about peak flow and environmental control.

Table 1: Pilot Data on Provider Behavior during Audio-taped Asthma Visits (N=12)

Provider Behavior	
Education about environmental trigger control	An average of 6 different areas covered (range 3-12)
Education about medications, spacers, and peak flow	An average of 13 different areas covered (range 3-27)
Demonstrates how to use spacers	1 visit
Demonstrates how to use inhalers	1 visit
Demonstrates how to use peak flow meters	None
Includes child input into asthma management regimen	33% of visits
Includes caregiver input into asthma management regimen	33% of visits
Provider asks child questions about asthma management	Asks child an average of 6.5 questions (range 0-22)
Provider asks caregiver questions about asthma management	Asks caregiver an average of 9.4 questions (range 0-30)

C.3 Pilot Study of the Home Interviews

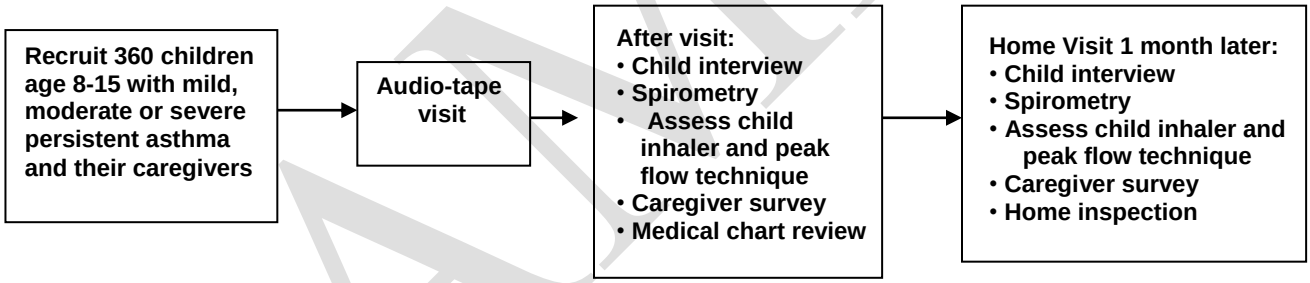
The home visit protocol – child interview and lung function test, caregiver survey, and home inspection – was completed with six families. The children ranged in age from 8 to 12 years. The entire home visit protocol required an average of 50 minutes to complete. The research assistant took an average of 32 minutes (range 20 to 45 minutes) to complete the child interviews (which included demonstrating inhaler and peak flow technique), 10 minutes to conduct spirometry, and 7 minutes to complete the home inspection. The children were shown response category cards and asked to identify their responses using these cards. The children thought the interview questions were clear and the response options appropriate. During this time, the caregivers completed the survey, which took approximately 32.5 minutes (range 20 to 45 minutes). The caregivers suggested a few wording changes to their surveys which we incorporated into our final instruments.

D. Methods

D.1 Overview

The study will involve recruiting a sample of 360 children ages 8 through 15 with mild, moderate, or severe persistent asthma and their caregivers at eight pediatric clinics in North Carolina. We will audio-tape record the medical visits with providers, children, and caregivers. Immediately after the medical visits, the research assistants will interview the children using a semi-structured questionnaire, observationally assess child inhaler and peak flow technique, and measure lung function using spirometry. Caregivers will fill out self-administered questionnaires after the medical visits. The research assistants will review the child's medical chart after the visit for information about the child's asthma, medications, and co-morbidities. A home visit will occur one month after the medical visit. Research assistants will again interview children, observationally assess child inhaler and peak flow techniques, and measure lung function. Caregivers will fill out a questionnaire at the home visit and an environmental trigger home inspection will be conducted. Figure 2 presents the study protocol.

Figure 2: Study Protocol



D.2 Setting

Thirty-five physicians at eight pediatric practices will be recruited to participate in the study. The investigators will obtain informed consent from physicians and their nurses. Table 2 presents the pediatric practice characteristics. Cary Pediatrics is within 20 minutes of the University of North Carolina. Four of the practices (Salisbury, Thomasville and Archdale, Guilford Child Health, and Lexington) are about an hour and a half west of UNC but they are within 30 miles of one another. Three of the clinics (Purcell, Sandhills, and Children's Health of Carolina) are approximately one hour south of UNC but they are within 30 miles of one another. We intend to hire research assistants who live regionally near the clinics. One research assistant will be assigned to each clinic during the 18 month enrollment period for each clinic. Dr. Sleath is successfully using this strategy in a large study being conducted in NC rheumatology clinics. The assistants will travel to Chapel Hill for the monthly project meetings and Dr. Sleath or another project team member and the project manager will travel twice monthly to meet with the research assistants at each clinic. Appendix B contains letters of support from participating practices. Guilford Child Health is a public clinic and the other seven clinics are private. However, most of the private practices serve very diverse populations and many of the practices serve a low socioeconomic population as evidenced by the percent of patients on Medicaid (see Table 2).

Table 2: Pediatric Practice Characteristics

Practices	Practice Size	# of Physicians	% African American patients	% Hispanic patients	% White patients	% Native American patients	% on Medicaid
Salisbury Pediatrics	53,000	11	20%	10%	69%	0%	35%
Thomasville and Archdale Pediatrics	25,000	14	28%	10%	61%	0%	50%
Guilford Child Health, Inc.	27,000	10	34%	20%	34%	2%	92%
Lexington Pediatrics	17,500	6	30%	15%	53%	1%	40%
Purcell Clinic	25,000	6	50%	2%	30%	8%	70%
Children's Health of Carolina	32,000	8	33%	2%	31%	34%	65%
Sandhills Pediatrics, Inc.	12,000	8	32%	15%	50%	3%	47%
Cary Pediatrics	30,000	15	20%	3%	75%	0%	7%

D.3 Patient eligibility and enrollment

Children will be eligible if they: (a) are ages 8 through 15 years, (b) are able to speak English, (c) can read the assent form, (d) have been seen at the clinic at least once before, (e) are present at the visit with an adult caregiver (parent or legal guardian) who can read and speak English and who is at least 18 years of age, and (f) have mild, moderate, or severe persistent asthma. Persistent asthma is defined as experiencing asthma daytime symptoms more than twice a week or asthma nighttime symptoms more than twice a month and/or receiving one or more long term controller therapies for asthma (NHLBI, 1997; Cabana et al. 2004). After talking with administrators and physicians at the participating clinics and reviewing U.S. Census Bureau Data for North Carolina (2000) we estimate that approximately 50% of the Hispanic families will speak English and will be able to participate in the study. We describe our rationale for excluding Spanish-language dominant children and caregivers in Section D.11 and recognize this as a limit of the study.

There will be a 36-month enrollment period. We intend to enroll patients at four clinics for the first 18 months of the enrollment period and at four different clinics for the last 18 months of the enrollment period. Each clinic will receive $500 a month for each month that they assist with enrollment of patients into the study. This money will partially support the salary of a clinic staff member who will help identify eligible patients and serve as the liaison to the study team. A UNC research staff person will work with the clinic liaison to identify the best time to recruit eligible patients and their caregivers. This may involve the UNC research staff person being at the clinic during typically busy times of the day and days of the week. Where possible, however, potentially eligible patients and their caregivers will be identified before their visit to the clinic. In these instances, the clinic staff member will call the caregivers of potentially eligible patients prior to their visit and briefly explain the study. The clinic staff member will ask the caregiver to bring in the child's asthma medications to the medical visit. The average no-show rate across the different clinics is 20 to 25 percent. This should not pose a problem for enrollment since we can catch these eligible patients at their next appointments. This has worked well in the study Dr. Sleath is currently conducting in NC rheumatology clinics.

Because enrollment into the study requires that the child have persistent asthma and because we intend to stratify by asthma severity to obtain a representative sample of children with mild and moderate/severe persistent asthma, we propose to have caregivers fill out a validated screening instrument (Lewis et al. 2004; Joseph et al. 1996; Clark et al. 2002, Appendix C). The screener has been validated against physician diagnosis and post-exercise hyper-responsiveness (Joseph et al. 1996; Clark et al. 2002). The screening instrument consists of eight questions and allows the classification of children into asthma severity categories defined by the National Asthma Education and Prevention Program (NAEPP) 1997 report. A child's asthma will be considered moderate-to-severe persistent if the following were reported: (a) any daytime symptom present every day, or (2) nighttime symptoms more than once a week or every night, or (3) daily use of doctor-prescribed medication with any daytime symptom reported as present more than two times per week. A child's asthma will be considered mild persistent if he or she does not meet any of the above criteria for moderate-to-severe persistent asthma and any of the following are true: (1) report of three or more daytime symptoms present more than two times per week, (2) report of any use of doctor-prescribed asthma medicines and two or more daytime symptoms present more than two times per week, or (3) report of daily use of doctor-prescribed medicine and nighttime symptoms present more than two times per month.

We intend to enroll five children with mild persistent asthma and five children with moderate/severe persistent asthma for each participating physician in each of the eight clinics. The maximum allowable number of children with mild persistent asthma per participating physician will be five. However, we will relax this inclusion criterion within 3 months of enrollment termination with permission from all parties involved, and allow enrollment of up to nine children with mild persistent asthma. We want to ensure that there is no chance of enrolling additional children with moderate or severe persistent asthma. This will allow us to minimize the possibility of enrolling predominantly children with mild persistent asthma. The number of moderate or severe patients may vary from zero to seven, but we anticipate recruiting at least three children with moderate/severe persistent asthma for each participating physician. It is important to note that this preliminary determination of whether a child has mild persistent or moderate/severe persistent asthma will only be used for sampling purposes and will not be used in analyses. Drs. Davis and Williams will determine asthma severity after the medical visit using the medical record, study-measured spirometry, caregiver questionnaire, and child interview data as described in Section D.6.d and these results will be used in our analyses.

We visited all eight clinics who have agreed to participate in the study and asked them about the percentage of children who have mild, moderate, and severe persistent asthma. The clinics were unable to give us a definitive answer to this question, although several noted that as a result of spirometry and other diagnostic strategies, they are beginning to realize that they care for a larger number of moderate persistent asthma patients than they originally thought. Misclassification or lack of classification is supported by the results of a recent study conducted by Cabana and colleagues (2003). The researchers found that only 34% of primary care pediatric university-owned clinics documented asthma severity in their medical records in the last 2 years. We estimate that approximately 10 percent of the children in each practice will have asthma, and of those, approximately 40 percent of the children are between ages 8 through 15 (yielding approximately 4% of each practice's population potentially eligible to participate in this study). This is a conservative given that 13.4% of children between 1-17 years of age have asthma in North Carolina (BRFSS, 2002). We then used validated asthma severity estimates from a nationally representative survey (Fuhlbrigge et al. 2002) to estimate the percent of children with asthma between ages 8 through 15 in each practice with a diagnosis of mild persistent or moderate/severe persistent asthma. This study found that approximately 36 percent of children with asthma had moderate/severe persistent asthma and 21 percent had mild persistent asthma (Fuhlbrigge et al. 2002). These estimates are similar to estimates given by Lewis et al. (2004). Our final estimates of 5,051 children ages 8 through 15 with persistent asthma (Table 3), indicate that we will easily reach our total target enrollment of 360 children with mild, moderate, or severe persistent asthma.

Table 3: Estimated number of asthmatic children by practice

Practices	**Practice Size**	**Estimated # of children with asthma between the ages of 8 and 15 (4% of practice)**	**Estimated number of mild persistent (21% of children with asthma between 8-15)**	**Estimated number of moderate or severe persistent (36% of children with asthma between 8-15)**
Salisbury Pediatrics	53,000	2120	445	763
Thomasville and Archdale Pediatrics	25,000	1000	210	360
Guilford Child Health, Inc.	27,000	1080	227	389
Lexington Pediatrics	17,500	1000	147	252
Purcell Clinic	25,000	800	210	360
Children's Health of Carolina	32,000	1280	269	461
Sandhills Pediatrics, Inc.	12,000	480	101	173
Cary Pediatrics	30,000	1200	252	432
			1861	**3190**

Clinic staff will refer interested and potentially eligible families to the research assistant. After the UNC research staff person administers the asthma severity screening instrument and determines if the child and caregiver are eligible, she or he will explain the study and obtain caregiver informed consent and child assent. As part of the consent process, caregivers will be asked to read a few lines from the consent form and we will assess their understanding of what is read (the purpose of the study, what they are being asked to do, what they will get from participating, and what they can do if they feel uncomfortable during the study). Caregivers who cannot read and understand the consent form will be excluded, because we will take this as an indication of low literacy and an inability to complete the study questionnaires. We describe our rationale for excluding caregivers who cannot read and understand sections of the consent form in section D.11 and recognize this as a limit of the study.

Based on our prior research (Sleath et al. 2003; Sleath et al. 2002), we anticipate that approximately 80 percent of approached eligible children and caregivers will participate. After obtaining informed consent and completing the data collection protocol (see D.4), the UNC research staff person will obtain contact information from the caregiver (Appendix C). We will also ask the caregiver for the names and contact information of three other individuals we can call if we are having trouble locating the caregiver for the one-month follow-up interview. The UNC research staff person will also give the caregivers his/her business card with study contact information including the toll free number of the asthma project.

Prior to completing the medical visit protocol, the research assistants will schedule the one-month follow-up home visits with the caregivers. We are conducting the second interview one month after their clinic visit so that we can examine the relationship between provider-caregiver-child communication and outcomes. If we wait longer than one month, other events might happen that could influence the relationship between communication during the visit and outcomes. If the home visit cannot be scheduled at that time, the UNC research staff person will contact the caregiver two weeks after the medical visit to set up an appointment. A postcard confirming the time and date of the scheduled home visit will be sent one week before the scheduled visit. The UNC research staff person will also call the caregiver the day before the scheduled visit to confirm the appointment.

D.4 Data Collection Protocol

Table 4 presents the data collection schedule. After consenting to participate in the study, the children and caregivers will then have their medical visits audio-tape recorded. We will audio-tape the child and caregiver's interaction with the physician and nurse, because in some practices, the nurse provides additional asthma education. After the medical visit is audio-tape recorded, the research assistant will conduct an interview with all participating children, observationally assess their inhaler and peak flow techniques, and measure their lung function using a spirometer. Caregivers will fill out a questionnaire. A MDILog will be placed on the child's controller medication. A MDILog is an electronic device which monitors patient adherence (Medtrac Technologies, Lakewood, CO). If the caregiver has not brought in the child's medication, the research assistant will give the caregiver the MDILog to put on the child's controller medication. The research assistant will show the caregiver how to do it and give the caregiver written instructions. The research assistant will also write down what medication the caregiver should put it on. The research assistant will call the caregiver the next day to make sure the MDILog was put on the medication. If the caregiver reports not being able to do it, the research assistant will travel to the child's home to place the MDILog on the medication. Appendix C contains a copy of the interview instruments and caregiver questionnaire. Children will receive a $15 gift certificate to a bookstore for the interview after the medical visit and caregivers will receive $15 for filling out the questionnaire.

After the child and caregiver have left the provider's office, the research assistant will review each child's medical chart for the one year period prior to the audio-taped visit using an abstraction tool (Appendix C).

One month after the audio-taped medical visit, the research assistant will conduct a home visit. Based on our preliminary studies, we anticipate that the entire home visit protocol will take approximately 50 minutes. As indicated in our preliminary studies, the home visit protocol will include: child interview, assessment of child inhaler and peak flow techniques, caregiver questionnaire, spirometry, and a home inspection. In addition, the research assistant will collect the MDILog that is on the child's controller medication. Appendix C contains a copy of all data collection instruments. Children will be given a $15 gift certificate to a bookstore for the home interview and caregivers will receive $15 for filling out the questionnaire.

Drs. Sleath and Ayala will meet weekly with the project manager. The entire project team will meet monthly and the liaisons from participating clinics will travel to Chapel Hill. One of the investigators will visit each clinic at least twice per month.

Table 4: Data Collection Schedule

Variable	Measure	Source	Schedule
Primary Aims			
Medication adherence (to controller medicine)	1-item; use has been 5-6 days a week in past 4 weeks	Child interview Caregiver survey	After visit and one month later
Medication adherence (to controller medicine)	MDILog		One month period between audio-taped visit and home visit
Inhaler technique	9 items	Observation of child	After visit and one month later
Peak flow technique	4 items	Observation of child	After visit and one month later
Child satisfaction	12 items	Child interview	After visit
Caregiver satisfaction	26 items	Caregiver survey	After visit
Secondary Aims			
Child asthma management self-efficacy	Bursch 14-items	Child interview	After visit and one month later
Caregiver asthma management self-efficacy	Bursch 13-items	Caregiver survey	After visit and one month later
Child outcome expectations	Holden et al. 5 items	Child interview	After visit and one month later
Caregiver outcome expectations	Holden et al. 5 items	Caregiver survey	After visit and one month later
Symptom monitoring (peak flow use)	2 items	Child interview Caregiver survey	After visit and one month later
Environmental trigger control		Child interview Caregiver survey Home inspection	After visit and one month later Home visit
Child quality-of-life	Juniper 23 items	Child interview	After visit and one month later
Caregiver quality-of-life	Juniper 13 items	Caregiver survey	After visit and one month later
Lung functioning	Spirometry Peak flow	Spirometry	After visit and one month later
School absences during past 2 weeks	1 item	Caregiver survey	After visit and one month later
ER visits during past month	1 item	Caregiver survey	After visit and one month later
Unscheduled physician visits for asthma during past month	1 item	Caregiver survey	After visit and one month later
Asthma symptom days during past two weeks	4 items	Caregiver survey	After visit and one month later
Communication measures			
Asthma management communication	Transcript coding tool	Transcripts of audio-tapes	Audio-taped visit
Modeling of asthma care behaviors	Transcript coding tool	Transcripts of audio-tapes	Audio-taped visit
Engagement of child during medical visit: Child input into asthma management regimen # questions provider asks child	Transcript coding tool	Transcripts of audio-tapes	Audio-taped visit
Engagement of caregiver during visits: Caregiver input into asthma management regimen # questions provider asks caregiver	Transcript coding tool	Transcripts of audio-tapes	Audio-taped visit
Other measures			
Asthma responsibility	McQuaid 10 items	Child interview Caregiver survey	After visit and one month later
Affective response	PACT-PORT, 10 items	Child interview Caregiver survey	After visit and one month later
Psychosocial stressors	24-item Impact-of- Illness on Family Scale	Caregiver survey	After visit and one month later
Need for prednisone in past month	1 item	Caregiver survey	After visit and one month later
Need for rescue medication in past month	1 item	Caregiver survey	After visit and one month later
Asthma Severity		Caregiver survey Medical records Spirometry	After visit
Child and caregiver demographics	Multiple items	Child interview Caregiver survey	Before visit
Co-morbidities	Chart abstraction	Medical records	After visit
Provider characteristics		Physician survey Nurse survey Practice characteristics	Before data collection begins

D.5 Transcription and Coding of Audio-tapes

Transcription of the audio-tapes. All of the audio-tapes will be transcribed under the supervision of the principal investigator. Having transcriptions of the medical visits makes the coding of the audio-tapes more reliable (Waitzkin 1990; Mishler, 1984). The transcribing rules used in this study have been used by Dr. Sleath before and were adapted from transcribing rules used by previous researchers in the area of physician-patient communication (Waitzkin, 1990; Mishler, 1984). All identifiers will be removed when the audio-tapes are transcribed. The transcriptionists will be blinded to the study hypotheses.

Refinement of the coding instrument. The transcripts will be coded using the instrument developed during our pilot study (see Appendix A). The coding instrument will measure: (a) asthma management education provided during the visit, (b) provider use of modeling/skill development during the visit, (c) provider engagement of the child during the visit, and (d) provider engagement of caregiver during the visit. Each of these measures is discussed further in section D.6.c below (measurement section).

Coding training. Dr. Sleath will train the research assistants how to code the transcripts using the coding instruments, which are discussed below. The coders will be blinded to the study hypotheses.

Coders will receive training using the 12 transcripts from the pilot study. During training, 0.80 will be used as a floor for coder inter-rater reliability. Practice and training will continue until this minimum level reliability is achieved. This minimal level of 0.80 has been achieved by Dr. Sleath in previous research studies (Sleath et al. 2003; Sleath et al. 2002; Sleath et al. 2001; Sleath et al. 1999). After coders have completed their training and achieved this minimal level of reliability, they will begin coding the actual transcripts. Spot checks of coder performance will be conducted throughout the coding process to assure that reliability levels are being maintained. If a problem in a coder's performance is detected, the coder will immediately be pulled from coding the transcripts and resume training until the minimum level of 0.80 is achieved.

D.6 Measures

To address the primary aims of this study, five indicators will be treated as primary outcomes. These include: medication adherence, inhaler and peak flow technique, and child and caregiver satisfaction. The following secondary outcomes will also be examined: symptom monitoring, environmental trigger control, child self-efficacy in asthma management, caregiver self-efficacy in asthma management, child outcome expectations, caregiver outcome expectations, child quality-of-life, caregiver quality-of-life, lung function, school absences, emergency room visits, unscheduled physician visits, and asthma symptom days. Secondary measures will be collected to augment the primary measures. We will also collect demographic and other measures for descriptive purposes and for possible inclusion as covariates. Each of these measures is discussed below.

D.6.a Primary Outcome Measures

Medication adherence to controller medicine:

Our main measure of treatment adherence is controller medication adherence. We will measure controller medication adherence in three ways, parent self-report, child self-report, and MDILogs (Medtrac Technologies, Lakewood, CO). Self-reported adherence will be measured as a dichotomous variable (1=has used controller medication on average 5-6 days a week during the past 4 weeks, 0=has not used controller medication on average 5-6 days a week during the past 4 weeks). Previous research suggests that this operationalization of controller medication adherence is associated with use of reliever medication and asthma symptom days (Finkelstein et al. 2002; Lozano et al. 2003).

Adherence using MDILogs will be measured using the following formula: adherence= (number of actuations recorded by the MDILog divided by the number of prescribed actuations) multiplied by 100. Newer controller medications include counters and other readings of dose. If a child is taking a controller product with a dry powder inhaler, device readings will be taken if included in the design of the product (e.g. Advair, Diskus). For, the Aerolizer, we can count the number of capsules the patient has used during the month following the medical visit. Poor adherence will then be measured as a continuous variable and as a dichotomous variable (mean adherence of less than 70% of prescribed doses; mean adherence of 70% or more of the prescribed doses) (Apter et al. 1998).

Inhaler technique: Children will demonstrate how they use their metered-dose inhalers using empty inhalers. The research assistant will record the number of steps done correctly out of nine possible steps. Dr. Williams will train the research assistants how to evaluate performance using an existing set of video-tapes, and inter-rater reliability will be calculated. This method has been validated in previous research by Dr. Williams (Gray et al. 1994). Correct use of inhalers will be measured as a continuous variable ranging from zero to nine.

Peak flow technique: Children will demonstrate how they use a peak flow meter using one provided by the project team. The research assistant will record the number of steps done correctly out of four possible steps. This method has been validated in prior research (Scarfone et al. 2002). Correct use of a peak flow meter will be measured as a continuous variable ranging from zero to four.

Child satisfaction: A 12-item Child Satisfaction Questionnaire will be used to measure provider-child rapport and the child's comfort with communication during the medical visit (Rifkin et al. 1988). The instrument has been validated for use in children ages 6 to 14 and has a Cronbach's coefficient alpha of 0.89. Previous research demonstrates that the Child Satisfaction Questionnaire is significantly associated with children's descriptions of providers on an adjective checklist measure (Rifkin et al. 1988).

Caregiver satisfaction: Caregiver satisfaction will be measured using the 26-item Caregiver Medical Interview Satisfaction Scale. Previous research has demonstrated that this scale is significantly associated with objective ratings of provider interpersonal skill during medical visits and it has a Cronbach's coefficient alpha of 0.92 (Bernzweig et al. 1997; Lewis et al. 1986, Lewis et al. 1991). The measure focuses on satisfaction with the communication during the medical visit, including communication with the caregiver and communication with the child.

D.6.b Secondary Measures

Child asthma management self-efficacy: Child asthma management self-efficacy will be measured as a continuous variable using a 14-item scale that has a reliability of 0.87 (Bursch et al. 1999). The self-efficacy scale has two subscales: confidence in preventing attacks (alpha=0.77) and confidence in managing attacks (alpha=0.82).

Caregiver asthma management self-efficacy: Caregiver asthma management self-efficacy will be measured as a continuous variable using a 13-item scale that has a reliability of 0.87 (Bursch et al. 1999). This self-efficacy scale has two subscales: confidence in preventing attacks (alpha=0.75) and confidence in managing attacks (alpha=0.82).

Child outcome expectations: Child outcome expectations will be measured as a continuous variable using an adapted version of Holden's scale designed for caregivers (Holden et al. 1998). We adapted Holden's scale for caregiver outcome expectations for use with children and will assess reliability.

Caregiver outcome expectations: Caregiver outcome expectations will be measured as a continuous variable. Caregiver outcome expectations will be measured using a 5-item scale that has a reliability of 0.72 (Holden et al. 1998).

Symptom monitoring will be measured as a dichotomous variable (0=child does not have peak flow meter or has a peak flow meter and does not regularly use it, 1=child has peak flow meter and regularly uses it at least twice per week). We will obtain this information from two questions, one that asks whether the child has a peak flow meter, and one which asks whether the child regularly uses it.

Environmental trigger control: Environmental control will be measured using a validated self-report measure (Finkelstein et al., 2002) and through home inspection using the North Carolina Environmental Checklist. The self report measure is a 24-item environmental control measure that assesses trigger control elements (e.g., plastic mattress covers) and trigger exposure in the home (e.g., pets, water build-up). Dr. Ayala has used this self-report measure during her involvement with the PAC-PORT study and we have used it successfully in our pilot home visit interviews. Our home inspection tool, the North Carolina Environmental Checklist, was developed for a four-county pilot asthma intervention project. The Asthma Management Through Low-Cost Environmental Intervention was funded by the North Carolina Department of Health and Human Services (NC DHHS) in 2001. The checklist measures exposure to indoor contaminants such as cockroaches, moisture and mold, pets and products of combustion (tobacco smoke, combustion space heaters), all of which have been identified in peer reviewed literature as asthma triggers in the indoor environment. The North Carolina DHHS still uses this checklist to conduct home assessments of asthma triggers.

We will also examine whether the caregiver and child report during the home visit that she/he acted upon environmental trigger control and prevention recommendations made by the provider during the medical visit. We will obtain the environmental trigger control and prevention recommendations made by the provider from the transcript of the audio-taped visit. Therefore, one additional measure of environmental control will be whether the caregiver and child acted upon one or more environmental trigger control and prevention recommendations made by the provider. Second, environmental control will be measured as a continuous variable, the number of environmental trigger control and prevention strategies that the caregiver and child stated that they worked on during the past month.

Child quality-of-life: Child quality-of-life will be measured as a continuous variable. We will use the standardized version of the Juniper pediatric asthma quality-of-life questionnaire. The questionnaire contains 23 items organized in three domains: symptoms, activities, and emotional impact of asthma, and has a reliability of 0.84 (Juniper et al. 1996). The questionnaire measures health-related quality-of-life in patients with asthma 7 to 17 years old and has proved reliable, valid, and responsive throughout the entire age range (Juniper et al. 1996a).

Caregiver quality-of-life: Caregiver quality-of-life will be measured as a continuous variable. We will use the Juniper caregiver asthma quality-of-life questionnaire. The questionnaire has 13-items and has a reliability of 0.85 (Juniper et al. 1996b). Four of the scale items address activity limitation and nine address emotional functioning.

Lung function: Lung function will be assessed using spirometry pre- and post-bronchodilator during the office visit and during the one-month follow-up home visit. Spirometry testing will be performed on a PDS Koko spirometer before and after administration of 2 puffs of CFC albuterol delivered through an Aerochamber holding device. Spirometry will be performed according to the standards of the American Thoracic Society (ATS, 1995). Percent predicted values will be based on data collected by Hankinson et al. 1999 (NHANES III). Spirometry provides conveniently obtained, reproducible data regarding airway obstruction. While physiologic measurement of airway function is less sensitive to changes in asthma status than other clinical measures, spirometry is inarguably the gold standard for management of patients with persistent asthma (NHLBI, 1997), and is more reproducible and effort independent than isolated peak flow measurement (Meltzer et al. 1989). The primary spirometry measurements we will evaluate are FEV_1 and FEF_{25-75}. Forced expiratory volume in one second (FEV_1) is the amount of air exhaled forcefully in the first second after a full inspiration, and is generally considered to be the best single measure for physiologic evaluation and monitoring in asthma. The FEF_{25-75} is considered to be a measurement of small airway function, and is thought to be the most sensitive (though more labile) physiologic measure of asthma control (Lebecque et al. 1993). The magnitude of improvement in these measures following bronchodilator demonstrates baseline bronchospasm and may be considered as an indicator of adequacy of asthma management. Dr. Davis will train the research assistants to conduct spirometry. The research assistants will go for training over a one month period at the University of North Carolina pulmonary function laboratory. Dr Davis will then regularly monitor and check their performance by examining all flow volume loops obtained on patients and periodically observing their testing technique throughout the study.

School absences during past two weeks: School absences will be measured as number of school absences due to asthma during the past two weeks. We realize that this measure is limited in that some children will not be in school when enrolled in the study. This information will be noted on the interview and survey instruments. Therefore, we will also measure the number of days with restricted or a significant change in activities due to asthma during the past two weeks. Caregivers will be shown calendars to aid their recall when asked these two questions. School absences and number of days with restricted or a significant change in activities due to asthma have been measured via self-report in prior research (Eggleston et al. 1998; Rosier et al. 1994; Yeatts et al. 2003)

Emergency room visits during past month: Number of emergency room visits will be measured as the number of ER visits during the past month. We are measuring them for the past month period since we are interviewing children and their caregivers approximately one month after their audio-taped medical visit. Caregivers will be shown calendars to aid their recall when asked this question. Number of emergency room visits has been measured via self report in prior research (Eggleston et al. 1998; Clark et al. 2000; Clark et al. 1998; Yeatts et al. 2003)

Unscheduled physician visits for asthma during past month: Number of unscheduled physician visits will be measured as the number of unscheduled physician visits made during the past month.

Asthma symptom days during past two weeks: Number of asthma symptom days will be measured as a continuous variable using the final of a series of four items. Caregivers will be asked how many times during the past fourteen days the child experienced the following: (a) wheezing, chest tightness, cough, or shortness of breath, (b) wakes up because of asthma, wheezing, chest tightness, cough, or shortness of breath, and (c) had to slow down or stop his/her play or activities because of asthma, wheezing, chest tightness, or shortness of breath. The last question asks the respondent to think about all three symptoms and report on the number of days the child experienced any of these symptoms during the day or at night (Lozano et al. 2003).

D.6.c Communication Measures

We selected our four main measures of communication (education, modeling/skill development, engagement of the child, engagement of the caregiver) using NHLBI guidelines for provider visits. In addition, we seek to examine the extent to which physicians and nurses in a pediatric setting discuss content associated with efficacious asthma management programs during medical visits. However, we can and will examine other dimensions of communication that appear to be important during analysis of the audio-tapes and transcripts of the medical visits.

Asthma management communication: Provider asthma management education will be measured as two variables: (a) education about environmental control/triggers and (b) education about medications, spacer, and peak flow monitor use. The variables will be continuous measures; we will calculate summary scores for each measure by combining the physician and nurse scores. We also will examine whether the physician and nurse provision of asthma management education about environmental control/triggers and education about medication, spacer, and peak flow monitor use are independently related to the outcome variables in our analysis.

The following will be recorded as asthma management education about environmental trigger control and prevention from the transcripts: (1) number of asthma triggers provider educates child and caregiver about and (2) number of environmental control areas provider educates child and caregiver about. The following will be recorded as education about medication/spacer/peak flow: (1) number of areas of information provided about rescue and control medications, (2) number of areas of information provided about using a spacer, and (3) number of areas of information provided about using peak flow meters. Appendix A contains a draft of the coding rules, which specifies the categories under each of these areas.

Modeling/skill development of asthma care behaviors: Modeling of asthma care behaviors will be measured as a continuous variable. We will calculate a summary score of modeling of asthma care behaviors that combines the physician and nurse scores. We will also examine how the physician and nurse modeling of asthma care behavior scores are independently related to the outcome variables in our analysis.

The following will be recorded as modeling of asthma care behaviors from the transcripts: (1) provider demonstrates how to use inhalers, (2) provider demonstrates how to use spacer, (3) provider demonstrates how to use peak flow meter, (4) provider asks child to demonstrate how to use inhalers, (5) provider asks child to demonstrate how to use spacer, (6) provider asks child to demonstrate how to use peak flow meter, and (7) provides a written asthma action plan.

Engagement of child during medical visit/child-centeredness: Provider engagement of the child during the medical visit will be measured as two variables: (a) provider includes child input into asthma management regimen (dichotomous; yes/no) and (b) number of questions provider asks the child about asthma management. Provider question-asking of the child will be measured as a continuous variable. We will examine overall question-asking but then we will separately examine open and close-ended question asking.

Engagement of caregiver during visit/caregiver-centeredness: Provider engagement of the caregiver during the medical visit will be measured as two variables: (a) provider includes caregiver input into asthma management regimen (dichotomous; yes/no) and (b) number of questions provider asks the caregiver about asthma management. Provider question-asking of the caregiver will be measured as a continuous variable. We will examine overall question-asking but then we will separately examine open and close-ended question asking.

D.6.d Other Measures

Child asthma responsibility: Asthma responsibility from the child's perspective will be measured as a continuous variable. Child asthma responsibility will be measured using a 10-item scale that has a reliability of 0.78 (McQuaid et al. 2001).

Caregiver asthma responsibility: Asthma responsibility from the caregiver's perspective will be measured as a continuous variable. Caregiver asthma responsibility will be measured using a 10-item scale that has a reliability of 0.87 (McQuaid et al. 2001).

Affective response to asthma: Affective response will be measured using 10 questions with a response option of 1=all of the time to 5=none of the time. Items assess feelings such as frustration, depression, upset, and anger. A higher score denotes less negative feelings toward their illness. Greater negative feelings have been found to be more common among non-adherent adolescents who do not adhere to treatment recommendations (Ayala et al., under review).

Psychosocial stressors: We will assess psychosocial stressors by having the caregiver complete the Impact of Illness on Family Scale (Stein and Riessman, 1980). It is a 24-item scale that evaluates the impact of a child's illness on family functioning. The questionnaire has four domains: financial, family/social, personal strain, and mastery. Responses to each item are given on a four-point Likert-type Scale (strongly agree to strongly disagree). Internal consistency (Cronbach's alpha) for overall impact and each domain ranges from 0.60 to 0.88.

Need for prednisone in past month: Caregivers and children will be asked whether their child used prednisone during the past month.

Need for rescue medication in past month: Children and caregivers will be asked the extent to which the child used his/her rescue medication in the past month. The response categories will be: never, once, 2-4 times, 5-7 times, and > 8 times.

Asthma severity:
Drs. Davis and Williams will review the study-measured spirometry, medical record, caregiver questionnaire, and child interview data to determine a child's asthma severity. Dr. Schechter will provide expertise and support to Drs. Davis and Williams on classification of asthma severity using these data sources. Asthma severity will be classified as mild, moderate or severe persistent based on the criteria recommended in EPR II report (NHLBI, 1997): Guidelines for the diagnosis and management of asthma*:

Mild Persistent:	Symptoms > 2 times a week, but < 1 time a day Nighttime symptoms more than twice a month FEV1 of at least 80% predicted, or PEF variability of 20-30%
Moderate Persistent:	Daily symptoms or daily use of a rescue inhaler Exacerbations that affect activity Exacerbations $\geq$ 2 times weekly Nighttime symptoms more than once a week FEV1 of 60 to 80% or PEF variability > 30%
Severe Persistent:	Continual symptoms Limited physical activity due to asthma Frequent exacerbations Nighttime symptoms frequently FEV1 $\leq$ 60% or PEF variability >30%

*The presence of any one of these findings places the patient in the higher category.

The National Heart, Lung, and Blood Institute guidelines define severity based on clinical features before treatment; therefore, frequent breakthrough symptoms occurring in the presence of daily controller therapy can be considered to represent more severe asthma (Lewis et al. 2004). Consequently, in addition to the above criteria, a child's asthma will be considered moderate persistent if there is reported daily use of doctor prescribed medication with any daytime symptom reported as present more than two times per week. A child's asthma will be considered mild persistent if he or she does not meet the above criteria for moderate persistent asthma and there is any reported use of doctor-prescribed asthma medicines and two or more daytime symptoms present more than two times per week or there is reported daily use of doctor-prescribed medicine and nighttime symptoms present more than two times per month (Lewis et al. 2004).

D.6.e Demographic and other characteristics:

Table 5 contains a list of other variables that we will measure.

Table 5: Demographic and other information that will be collected

Child age, gender, ethnicity
Caregiver age, gender, ethnicity, educational status
Maternal and paternal educational attainment
Type of health insurance
Annual household income
Age of child asthma diagnosis
Physician age, gender, ethnicity
Nurse age, gender, ethnicity
Only physician does asthma education or both physician and nurse do asthma education
Number of prior visits to this physician
How long child and family has known physician
Duration of visit
Reason for visit
Affective response to asthma
Caregiver care expectations
Seasonality (month of year)
Environmental triggers

D.7 Data Management and Quality

Scales with sound psychometric properties have been selected for the proposed study wherever possible. To facilitate coding during patient interviews, close-ended interview items have been identified so that they are self-coded (interviewers will mark appropriate codes as respondents answer each question). Coding and data entry will be performed weekly as the data collection process is underway.

Interviewers will attend monthly staff meetings to monitor their data collection processes. Ten percent of all outcome data will be double entered. A comparison of the two entries will be made via computer for all endpoints/dependent variables. The SPSS data entry program only accepts values within the range specified for each variable. Ranges will be further checked at the time of index construction to assure each measure's data are in the appropriate range and computed correctly. Distribution frequencies will be examined for skewness or unusual outliers. Summary data will be examined to resolve any problems. As described above, primary dependent variables are being measured in multiple ways. Inter-measure consistency will be analyzed through correlations of matched measures. In addition to maintaining up-to-date data sets, the process of ongoing coding and data entry will serve the added function of monitoring for accuracy and completeness of the interviews, allowing for immediate corrections or modifications in interview or interviewer procedures.

Dr. Davis will train the research assistants how to abstract medical record information. She will then regularly monitor and check their performance by reviewing 10 percent of all of the records reviewed. All of the coders will abstract

information from the records that Dr. Davis reviews. Inter-rater reliability will be calculated between herself and the research assistants.

Dr. Davis will train the research assistants to conduct spirometry. The research assistants will go for training over a one-month period at the UNC pulmonary function laboratory. Dr. Davis will then regularly monitor and check their performance by examining all flow volume loops obtained on patients and periodically observing their testing technique first hand.

Dr. Williams will train the research assistants how to assess inhaler and peak flow technique. He will then regularly monitor the research assistants' performance on a monthly basis by observing the research assistants' assessment of inhaler and peak flow technique for 10 percent of the patients.

D.8 Sample Size and Statistical Power

Generalized estimating equations will be used to detect the difference in outcomes predicted by the independent variables. Effect size is a measure which can be used to assess the magnitude of the differences (Cohen, 1988; Kraemer and Thiemann, 1987). Effect size is defined as the measure of difference or change divided by the standard deviation. An effect size of 0.10 can be considered small, 0.30 as medium, and 0.50 as large (Cohen, 1988). Based on the previous literature, we expect medium effect sizes for independent variables predicting child outcomes (Wissow et al. 1998; Lewis et al. 1991).

In our previous research we have found that physician interaction style is not highly correlated within clinic site or physician and we estimate that the intra-physician correlation is below 0.2 for our outcome measures (Sleath et al. 2003; 2001). Our average cluster size is 10 patients and there are 35 physicians. Therefore, with a two-sided alpha of .05, a sample of 360 patients nested within 35 physicians will afford 80% statistical power to detect an effect size of 0.28 or a correlation of 0.2 (Snijders and Bosker, 1993; Kraemer and Thiemann, 1987). Prior studies of pediatric asthma that have followed families for a year have had attrition rates ranging between 18 and 21 percent (Krieger et al. 2002; Sharek et al. 2002). Since we are only following families for one month we expect an attrition rate of only 10 percent. Although we expect a 10% attrition rate, a sample size of 324 children will still allow us to detect an effect size of 0.30 or a correlation of 0.2 with 80% power. In our preliminary study (Sleath et al. 2002) we found a mean physician score of 37.5 points with a standard deviation of 15 points. An effect size of 0.3 would equate to a 12% improvement in the mean physician score. An increase (or decrease) in physician score of 10 points (a change of 27%) equates to an effect size of 0.67, which would be more clinically meaningful. In addition we hope to see correlation values of 0.30 or higher, thus, our study is adequately powered.

D.9 Analysis

Baseline comparisons

Characteristics of the children will be presented by clinic, by physician, and also by provider interaction style using several categories. Provider interaction style will be computed by summing up all raw scores across all four of the main areas of communication for the physician and the nurse involved in the visit. Just the physician's scores will be used if there is no nurse present. Thus, provider interaction style will reflect the total amount of asthma communication that occurs during the entire visit. Supporting analyses will look at each of the four areas of communication separately.

Statistical comparisons will be made between provider interaction style categories using means, standard deviations and analysis of variance, for continuous variables, and percents and chi-square tests for categorical variables. Similarly, baseline characteristics of dropouts and non-dropouts will be presented and compared using t-tests for continuous variables and chi-square tests for categorical variables.

Analysis of outcomes

General Comments

The goal of the planned analyses will be to test the five primary hypotheses (Aims 1-3) regarding medication adherence, inhaler and peak flow techniques, and satisfaction of the caregiver and child. We will use the Hochberg method so that our study-wise significance level will not be inflated (Koch 2000). The Hochberg method is an extension of the Bonferroni correction, where the overall type I error rate is held constant by testing each individual primary hypothesis at

an alpha level at or below the overall type I error rate. The individual component alpha levels are determined by the number of individual tests that are significant at the overall type I error rate of 5%. If all five primary hypotheses are tested and result in p-values of .05 or less, than all five will be considered significant. If only four tests result in p-values below .05 then they need to be less than .025 for the four to be considered significant. If only three tests results in p-values below .05 then they need to be less than 0.0167. If only two tests results in p-values below .05 then they need to be less than 0.0125. If only one primary hypothesis results in a p-value of .05 or less then it needs to be less than 0.01 in order to conclude that this one test is significant at the overall .05 level.

In support of the primary analyses this same methodology will be applied using the secondary outcomes involved in Aims 4-6 and the outcome, lung function, in Aim 7. The Hochberg method will not be employed for all other outcomes in Aim 7 due the possibility of very low prevalence and incidence estimates. The secondary analyses will only be considered significant if the original primary analyses were significant. The secondary hypotheses will serve as supporting analyses to enlighten the understanding of the primary hypotheses. Even if the primary hypotheses do not yield significant results, all secondary outcome variables will be analyzed and presented, but interpretation of the significance of the results will depend on the results of the primary analyses. For additional descriptive support and to see which area of communication that makes up the provider scores has the greatest effect, all analyses (i.e., all Aims) will be repeated with each of the four areas of communication.

Generalized estimating equations, (i.e., the GEE method, Diggle et al. 1994), will be used to analyze each aim. The GEE method is an extension of the generalized linear model. It accounts for the intra-physician correlation of data from the multiple subjects enrolled for each physician through its informative use in the computation of consistent estimates for model parameters and their corresponding covariance structure. The GEE method can incorporate inter-physician and inter-subject information into the analysis as well as the partially complete information from patients with data missing completely at random (MCAR). It also has the advantage of involving fewer assumptions, including no assumption about the distribution of the data. The GEE method, can handle both categorical and continuous outcome variables. The GEE method will allow us to make inferences across all subjects (and across physicians if so interested) while at the same time using the correct variance estimates that take into account the correlation within a given doctor. Covariates in the model can be at the provider level as well as at the subject level and may include practice, gender and ethnicity of the physician and of the nurse, and patient and visit characteristics (Table 5), but will always include the child's age, provider style score, as well as asthma severity of the patients as a stratification variable. By including asthma severity in our models, our estimates will be unbiased with regards to over-sampling children with moderate and severe asthma.

Aim 1: Medication adherence – measured 2 ways

Analysis of the first aim will include looking at two different endpoints. GEE will be used to test for an association between provider interaction style and whether the child uses their inhaler 5 to 6 times per week or not. This association will be tested at baseline and again at that the one-month visit. The primary analysis will be the one-month home visit adjusted for the baseline measure. In this way we will also be able to assess if provider interaction style is associated with a positive change in behavior. In addition, the correlation between the measurements at the two time points will be measured. GEE will also be used to test for an association between provider interaction style and MDILog dose measure at the one-month visit. For the primary result MDlLog may be used as a dichotomous or as a continuous variable, depending on its distribution.

Aim 2: Inhaler and peak flow technique

Inhaler technique will be originally used as a continuous variable, but if its distribution warrants, it will be treated as a categorical variable. An association between inhaler technique and provider interaction style will be assessed using GEE with similar models as outlined in Aim 1. The same technique will be used to assess the association between peak flow technique and provider interaction style.

Aim 3: Caregiver and child satisfaction

Satisfaction with the clinic visit will be assessed separately for the caregiver and the child. The correlation between the two scores will also be assessed. GEE will be used to assess the association between satisfaction and provider interaction style. The least significant test result of the two individual scores will be used when we assess significance with the Hochberg method.

Aim 4: Symptom monitoring and environmental trigger control
This secondary aim of examining symptom monitoring will be assessed using both peak flow monitoring and environmental trigger control. Both outcomes are dichotomous, but environmental control will also be treated as a continuous variable (see section D.6.b). GEE will be used to assess the association between each of these variables with provider style using similar models as outlined in Aim 1. Environmental trigger control will be assessed for all children and then again only using those children who received a recommendation from their provider to check on their environment. An interaction term involving provider's recommendation will be used to support the subgroup results. The direct inspection results on environmental control will be used to validate the child and caregiver responses.

Aim 5: Caregiver and Child Self-Efficacy and Outcome Expectations
Self-efficacy and outcome expectations will be assessed separately for the caregiver and the child. The correlation between the two scores will also be assessed. GEE will be used to assess the association between self-efficacy and provider interaction style, and between outcome expectations and provider style. The least significant test result of the two individual scores will be used when we assess significance with the Hochberg method. The two separate time points will be assessed as described in Aim1.

Aim 6: Caregiver and Child Quality of Life
GEE will be used to assess the association between QOL and provider interaction style with the same models as outlined in Aim 1.

Aim 7: Lung function, school absences, emergency room visits, unscheduled physician visits and asthma symptom days.
GEE will be used to assess the association between lung function, school absences, emergency room visits, unscheduled physician visits, asthma symptom days, and provider interaction style with the same models as outlined in Aim 1.

Other analysis considerations
All descriptive statistics on baseline and one-month results will be presented by practice and by physician and by a categorical version of provider interaction score. In the primary and secondary hypotheses, provider interaction style will be the sum of the physician's and nurse's communications, but in addition, as a supporting analysis, models will be rerun looking at physician interaction style separately (i.e., no nurses scores). All analyses will be performed using SAS.

All caregivers who agree to participate will be asked for the names and phone numbers of three other individuals who we can contact if we are having difficulty locating the caregiver. For those patients who we cannot reach via phone to schedule a home interview, we will contact these other individuals in an attempt to locate the caregiver. Also, we will send the caregivers letters with the study's toll free number asking them to call to reschedule their home interview. If a home interview cannot be conducted, at a minimum, descriptive data collected from non-respondents will enable us to determine whether they differ in certain important respects from respondents. Because we anticipate the proportion of non-respondents to be low, we anticipate that, even if they differ from respondents, adjustments will be possible for avoiding bias. For example, we may be able to impute values based on the average scores of similar people among the responders or to assign weights to data values to offset the impact of missing data. For the one-month outcomes, initially only patients with both baseline and one-month visit data will be used. In addition, we will rerun these analyses using imputed data for those patients with a missing value at one-month. Data sets and analyses both with and without imputation can be compared to one another to assess whether the missing data have a significant impact on results.

D.10 Timeline

Year 1 month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Hire & train staff												
Recruit, audio-tape, interview children & caregivers												
Conduct home interview 1 month after visit												
Transcribe audio-tapes												
Code audio-tapes												
Data set construction												
Analyze preliminary data												
Prepare annual report												
Year 2 month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Recruit, audio-tape, interview children & caregivers												
Conduct home interview 1 month after visit												
Transcribe audio-tapes												
Code audio-tapes												
Data set construction												
Analyze preliminary data												
Prepare annual report												
Year 3 month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Recruit, audio-tape, interview children & caregivers												
Conduct home interview 1 month after visit												
Transcribe audio-tapes												
Code audio-tapes												
Data set construction												
Analyze preliminary data												
Prepare annual report												
Year 4 month	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Recruit, audio-tape, interview children & caregivers												
Conduct home interview 1 month after visit												
Transcribe audio-tapes												
Code audio-tapes												
Data set construction												
Analyze preliminary data												
Prepare final report												

D.11 Methodological Considerations

1. We are examining only one medical visit at one point in time. Therefore, we do not know how provider, child, and caregiver behavior in previous visits may be influencing long-term outcomes. However, the clinical guidelines of the National Asthma Education and Prevention Program of NHLBI encourage physicians to discuss asthma management during every patient visit (NHLBI, 1997; NIH, 2002) so we believe that our study will provide new information on the extent to which these issues are discussed during pediatric visits.
2. Provider, caregiver, and child behavior could be influenced by the presence of a tape recorder during the medical visit. However, previous research has shown that the average length of physician-patient encounters with tape-recorders present is almost identical to the average length of physician-patient encounters reported in the National Ambulatory Medical Care Survey (Roter, 1991). Also, Dr. Sleath's prior work has found that communication about medications is still poor, even when providers know their visits are being audio-taped (Sleath et al. 2003; Sleath et al., 2002; Sleath et al. 1999).

3. We will be enrolling patients at four clinics during one 18-month period and at four different clinics during a different 18-month period. We choose to do this for logistical and budgetary reasons. To achieve an adequate sample size of providers, we need to enroll providers at eight clinics. It would be extremely costly to enroll patients at all eight clinics at the same time. We understand that there is the possibility that new asthma guidelines or medications may be introduced during our enrollment period that could potentially bias our results, but we believe that this would be highly unlikely. If this did happen during our study, we would attempt to control for this in our analyses.
4. Placing the MDILog on the child's inhaler may impact inhaler adherence. However, prior research has found that measuring adherence with electronic monitors is more accurate than patient self-report, evaluation by the patient's physician, or weighing canisters (Apter et al. 1998; Apter et al. 2001).
5. We are excluding families who are not English-language dominant. We estimate that approximately half of the Hispanic families will be excluded based on U.S. Census estimates and what we learned from the participating clinics. This clearly has implications for the generalizability of this study given the growing Hispanic immigrant population in the U.S. However, we argue for excluding non-English language dominant children and caregivers for the following reasons: a) a translator present during the medical office visit is likely to change the communication patterns between the provider, caregiver, and child; b) if a translator is not present, communication is likely to occur predominantly through an older sibling, as children of non-English speaking immigrants acquire English language skills faster than their caregivers; c) the predominant non-English speaking population in North Carolina is comprised of Mexican immigrants. Mexican immigrants represent less than 4% of the total North Carolina population. Given that asthma prevalence is lowest among Mexicans in comparison with other Latino subgroups (e.g., Puerto Ricans), that non-English speaking Latinos are still relatively underrepresented in the proposed geographic region, and that having an official translator or child translator will significantly alter the communication that occurs between providers, caregiver, and children, we argue for excluding non-English speaking persons at this stage of this research investigation.
7. After speaking with administrators and physicians from the clinics, we estimate that less than 10 percent of English-speaking caregivers will be unable to complete the caregiver survey due to low literacy. Therefore, we now intend to exclude caregivers who cannot read parts of the consent form and understand its contents. Ability to read and understand the consent form is a good indicator of ability to read and understand the survey given that they have been written at similar grade levels. Using methods employed in other studies with non-English dominant participants, we will ask caregivers to read aloud a few sentences from the consent form. If they are unable to read and understand the consent form, they will be informed about study requirements and thanked for their time. Asking the caregiver to participate in a face-to-face interview following the child interview would double the time required to complete the surveys immediately following the medical visit and during the home visit, and may lead to a greater refusal rate, more incomplete interviews, or greater attrition. We acknowledge however that excluding these individuals introduces some selection bias.

D.12 Summary

In summary, there is a need to better understand provider-caregiver-child communication about asthma during pediatric visits and how this impacts treatment adherence, inhaler and peak flow technique, and satisfaction as well as other outcomes. This will be one of the first studies to examine the extent to which physicians educate and involve children and caregivers in asthma management decisions, which the NHLBI guidelines suggest that providers should do at every visit (NHLBI, 1997; NIH, 2002). The findings from this study can be used to educate providers, caregivers, and children about how to optimize communication during pediatric asthma visits to assure improved child and caregiver outcomes. If we find that provider communication about asthma management, modeling, and engagement of the child and caregiver during medical visits is related to treatment adherence and other outcomes, we can then design intervention studies to improve communication between children, caregivers, and providers during pediatric asthma visits.

E. Human Subjects

1. Risk to Subjects (This information relates to all research sites).

Involvement

After consenting to participate in the study, the children and caregivers will then have their medical visits audio-tape recorded. We will audio-tape the child and caregiver's interaction with the physician and nurse, because in some practices, the nurse provides additional asthma education. After the medical visit is audio-tape recorded, the research assistant will conduct an interview with all participating children. The research assistants will assess child inhaler and

peak flow technique and lung function using spirometry. Caregivers will fill out a questionnaire. One month after the audio-taped medical visit, the research assistant will conduct a home visit. The research assistant will interview the child and assess child inhaler and peak flow technique and lung functioning. The child's caregiver will be asked to fill out a questionnaire.

Characteristics

Pediatricians will be eligible if they see children with mild, moderate, or severe persistent asthma. Children will be eligible if they: (a) are ages 8 through 15 years, (b) are able to speak English, (c) have mild, moderate, or severe persistent asthma, (d) are on a controller medication, (e) can read the consent form, (f) are present at the visit with an adult caregiver who can read and speak English, read and understand the consent form, and who is at least 18 years of age, (g) are patients of participating physicians, and (h) have been to the clinic at least once before.

Sources of Materials

Our data sources will include provider demographic surveys, caregiver surveys, interviews with the children, spirometry, and medical record data. The informed consent explicitly states what data will be collected. We will also have caregivers sign HIPPA forms.

Potential Risks

The primary risk is breach of confidentiality. However, the procedures that we have used in our pilot study have successfully protected against this; we plan to use the same procedures in this study. Code numbers will be assigned to children, caregivers, physicians, and nurses and any information that could identify children, caregivers, physicians, or nurses participating in this project will not be included in any data sets. Also, the audio-tapes will be transcribed into text and erased and all identifiers will be removed and replaced by blank lines.

Some children, caregivers, and providers may feel uncomfortable having their medical visits audio taped, although we anticipate that this will not be a problem. We have audio-taped medical visits in earlier projects and there were very few providers and patients who found it objectionable.

2. Adequacy of Protection Against Risks (This information relates to all research sites).

Recruitment and informed consent

Physicians and nurses at participating practices will be asked to participate in the study by one of the investigators. The study will be explained and the physicians and nurses will be asked to sign consent forms. We will then recruit children with asthma and their caregivers of physicians who agree to participate. Each clinic will receive $500 a month for each month that they enroll patients into the study. This money will partially support the salary of a clinic staff member who will help identify eligible patients and serve as the liaison to the study team. A UNC research staff person will work with the clinic liaison to identify the best time to recruit eligible patients and their caregivers. This may involve the UNC research staff person being at the clinic during typically busy times of the day and days of the week. Where possible, however, potentially eligible patients and their caregivers will be identified before their visit to the clinic. In these instances, the clinic staff member will call the caregivers of potentially eligible patients prior to their visit and briefly explain the study. The clinic staff member will ask the caregiver to bring in the child's asthma medications to the medical visit. On the date of the medical visit, the clinic receptionist will refer those caregivers and children who expressed an interest in learning more about the study to a research assistant in the waiting room. All study procedures will be explained fully to the child and caregiver, and the research staff person and the physician will be able to answer any questions the child or caregiver has about the study. All caregivers will be asked to sign a consent and HIPPA form and children will be asked to sign an assent form. The signed consent, assent, and HIPPA forms will be kept in a locked file cabinet and copies will be given to the caregivers and children.

Protection against risk

Informed consent will be obtained from all children, caregivers, and providers who participate in the study. All data will be stored in a secured fashion. Code numbers will be assigned to children, caregivers, physicians, and nurses and any information that could identify children, caregivers, physicians, or nurses participating in this project will not be included in any data sets. Also, the audio-tapes will be transcribed into text and erased and all identifiers will be removed and replaced by blank lines.

3. Potential Benefits of the Proposed Research to Subjects and Others (This information relates to all research sites).
The benefits are potentially great if the knowledge we gain from this study can be used to improve services for children with asthma and their caregivers in pediatric settings.

4. Importance of Knowledge to be Gained
This application helps address gaps in the literature about communication between providers, caregivers, and children with asthma in private pediatric practices. This will be one of the first studies to examine the extent to which providers educate and involve children and caregivers in asthma management decisions, which the NHLBI guidelines suggest that providers should do at every visit (NHLBI, 1997; NIH, 2002). The findings from this study can be used to educate providers, caregivers, and children about how to optimize communication during pediatric asthma visits to assure improved child and caregiver outcomes. If we find that provider communication about asthma management, modeling, and engagement of the child and caregiver during medical visits is related to treatment adherence and other outcomes, we can then design intervention studies to improve communication between children, caregivers, and providers during pediatric asthma visits.

5. Collaborating Sites
Eight pediatric practices have agreed to participate in the study. They are described in section D.2 above. Clinic staff will contact eligible participants and refer them to UNC employees who will obtain consent and enroll participants into the study as we have described above.

6. Inclusion of Women and Minorities
We expect about half of our sample of children to be female. We expect our child and caregiver samples to be 30% African American, 7% Hispanic, and 4% American Indian. The tables below present the gender, ethnic, and racial breakdown of our planned enrollment of subjects.

Planned Enrollment of the Physician Sample

Ethnic category	**Male**	**Female**	**Total**
Hispanic or Latino	1	0	1
Not Hispanic or Latino	20	14	34
Total	21	14	35

Racial categories	**Male**	**Female**	**Total**
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Black or African American	2	1	3
Native Hawaiian or Other Pacific Islander	0	0	0
White	19	13	32
Other	0	0	0
Total	21	14	35

Planned Enrollment of the Nurse Sample

Ethnic category	**Male**	**Female**	**Total**
Hispanic or Latino	0	1	1
Not Hispanic or Latino	3	26	29
Total	3	27	30

Racial categories	**Male**	**Female**	**Total**
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Black or African			

American	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
White	3	26	29
Other	0	0	0
Total	3	27	30

Planned Enrollment of the Child Sample

Ethnic category	**Male**	**Female**	**Total**
Hispanic or Latino	13	12	25
Not Hispanic or Latino	167	168	335
Total	180	180	360

Racial categories	**Male**	**Female**	**Total**
American Indian/Alaska Native	7	7	14
Asian	0	0	0
Black or African American	60	60	120
Native Hawaiian or Other Pacific Islander	0	0	0
White	113	113	226
Other	0	0	0
Total	180	180	360

Planned Enrollment of the Caregiver Sample

Ethnic category	**Male**	**Female**	**Total**
Hispanic or Latino	3	22	25
Not Hispanic or Latino	33	302	335
Total	36	324	360

Racial categories	**Male**	**Female**	**Total**
American Indian/Alaska Native	2	12	14
Asian	0	0	0
Black or African American	12	108	120
Native Hawaiian or Other Pacific Islander	0	0	0
White	22	204	226
Other	0	0	0
Total	36	324	360

7. Inclusion of Children

Our application focuses on communication about asthma during pediatric visits, so we will be enrolling 360 children into the study.

F. Vertebrate Animals: N/A

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I. Consultants

Patricia Bush, Ph.D., is a leading expert on medicine use in children and especially medicine information needs of children. Although retired, she is still actively involved with UNC's Center on Research and Education on Therapeutics of medicine use in children that is funded by the Agency for Healthcare Research and Quality. Recently, she published with Drs. Sleath and Pradel an article on the pharmacist's perspective on communicating with children about medicines. Previously, she and Dr. Sleath worked together on research for the United States Pharmacopoeia which involved evaluating the usefulness of medicine information leaflets among North Carolina residents. Also, she served on a UNC Chapel Hill student's Ph.D. committee, the research involving interviewing North Carolina children with asthma and their families. Currently, she is also a consultant to an SBIR Phase II grant to complete development of, and evaluate, a multimedia CD-ROM for adolescents with solid tumors; a research project in Moldova to involve schoolchildren in reducing inappropriate antibiotic use for colds and flu; and the development of medicine education curricula for Finnish schoolchildren. Dr. Bush has been a co- or principal investigator of 19 federally funded research grants on research on children's health behaviors and has published over 90 articles in this area. She will provide expertise on measurement to the project.

Michael Schechter, MD, MPH is a pediatric pulmonologist and epidemiologist on the faculty at Brown University. He recently relocated to Brown from Wake Forest University in North Carolina. Dr. Schecter has worked with many of the participating practices before. Dr. Schechter's research interests primarily relate to health care disparities in respiratory disease. He has worked in projects evaluating the impact of socioeconomic status on outcomes in cystic fibrosis, and is principal investigator of an ongoing multi-center quality improvement project funded by the Cystic Fibrosis Foundation. Dr. Schechter has also worked with health services researchers on analyses of N.C. Medicaid databases, and is currently the principal investigator on a project whose aims are to evaluate a screening tool for persistent asthma and to evaluate the impact of direct administration of asthma medication in the school setting. Dr. Schechter also brings to the project the clinical experience of a physician who spent twelve years in a private general pediatric setting and then ten years in a sub-specialty academic setting in North Carolina.

Robert D. Annett, Ph.D., an Associate Professor of Pediatrics at the University of New Mexico has expertise in the neuropsychological assessment of children with chronic medical conditions. His clinical work is with the Pediatric

Divisions of Pulmonary, Oncology, and Infectious Diseases, and he is Director of the Behavioral Pediatrics Clinic. Dr. Annett is an expert in the psychological factors associated with pediatric asthma. He is a Co-investigator in the Childhood Asthma Management Program (CAMP), a National Heart Lung and Blood Institute funded multi-center, masked, randomized, placebo-controlled clinical trial carried out in children with mild to moderate asthma and has been a member of the Steering Committee for the CAMP study. Dr. Annett has collaborated with other investigators within CAMP to examine the neuropsychological and psychological factors associated with disease treatment.