IMPLICATIONS OF FOOD ALLERGIES IN THE SEVERITY OF ASTHMA

By

Nancy L. Emery R.N., B.S.

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APPROVED:

[redacted]

Marsha L. Heims, R.N., Ed.D., Associate Professor,

School of Nursing, Oregon Health Sciences University

Research Advisor

[redacted]

M. Katherine Crabtree, DNSc, RNCS, ANP, Associate Professor

School of Nursing, Oregon Health Sciences University

Committee Member

[redacted]

Molly L. Osborne, M.D., Ph.D.

Department of Pulmonary Medicine, Oregon Health Sciences University

Committee Member

[redacted]

Carol A. Lindeman, R.N., Ph.D., Professor

School of Nursing, Oregon Health Sciences University

Dean

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ABSTRACT

TITLE: Implications of Food Allergies in the Severity Of Asthma

AUTHOR: Nancy L. Emery

APPROVED: Marsha L. Heims

Marsha L. Heims, R.N., Ed.D., Advisor

BACKGROUND: The role of food allergies in asthma has not been well described. Although the data are limited, food allergies might contribute to severity of asthma and health care utilization.

OBJECTIVE: The objective of this study was to evaluate the type of reactions and severity of reactions to food allergies in asthmatic patients.

METHODS: As part of a longitudinal, NIH-funded cohort study 553 patients ages 3 to 55 were identified as having medically diagnosed asthma from the automated pharmacy and hospitalization databases of a large health maintenance organization. A clinical evaluation included skin prick testing, spirometry, and a questionnaire that contained information on food allergies.

RESULTS: Overall, 240 (43.3%) participants reported adverse reactions to food. Subjects with food allergies tended to be older and were more likely to be female. The top three foods causing adverse reactions were milk or dairy products, eggs, and peanuts. Participants who reported adverse reactions to food had more severe asthma than those who did not report adverse reactions. However, this difference was not significant after adjusting for age and gender. Participants with food

allergies were more likely to report having ever been hospitalized for breathing problems than those without food allergies ($p<0.003$)) with the association again strongest in females ($p=0.011$).

CONCLUSIONS: These results indicate that, particularly in females, both severity of asthma and health care utilization are associated with self-reported food allergies. These findings suggest that the presence of food allergies may identify asthmatic patients who require closer health care management.

Key Words: asthma, food hypersensitivity, hospitalization, skin testing

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excluded many of the reactions that had been noted previously. Since that time, allergists have been divided concerning food reactions. One group, considered the orthodox camp, include those who only look at reactions that could be proven in vitro. It has been very difficult to test subjects scientifically in vivo because the antibodies that prove the scientific definition could only be proven by the examination of blood. The other group, considered the unorthodox camp, consisted of those who believed a wide variety of reactions could be caused by ingesting foods. These reactions may take longer to manifest and include some forms of depression or other states of mental illness as well as long term stomach illnesses such as colitis to name only a few. Because of this view the unorthodox practitioner was often and still is treated as a heretic in the medical professions.

Environmental agents such as pollens, danders and dust could easily be shown to trigger allergic reactions and did not threaten the economy. Financial and political interests were organized and lobbied strongly against restrictions related to food. Farmers, food manufacturers, and processors had a financial stake in not letting professionals declare such common foods as wheat, corn, sugar, milk and eggs as dangerous to even a small portion of the population.

The delayed removal of sulfites, a food preservative, from restaurant salad

bars is an example of how political powers can impede the use of knowledge about allergic reactions. As early as 1952, sulfite reactions

were cited in the literature. The Food and Drug Administration (FDA) did not act on the problem until 1982 when there were over 1,400 complaints about sulfites including 17 documented deaths. According to FDA estimates, one out of ten asthmatics are at serious risk from sulfite exposure. In 1985, the FDA proposed a regulation labeling foods that contain sulfites of at least 10 ppm. Later in the year they proposed another regulation that disallowed the use of sulfites on raw produce. Since 1986, when these regulations went into effect, packaged foods are now labeled although sulfites are still widely used in restaurants without the consumer's knowledge. The FDA's delay in acting has been attributed to pressure from food lobbyists (Randolph & Moss, 1990).

Chiaramonte and Altman (1991) state that in a survey of 173 physicians composed primarily of allergists, 81% said they were reluctant to handle food allergy complaints and 92% preferred to send such patients elsewhere. The most common treatment of patients with food allergies was to ignore those patient's complaints. The authors also suggest that health professionals and nutritionists need to reach agreement on the standardization of diagnosis and treatment of food allergies. Furthermore, they recommend that the term food allergy should be abandoned and the term food sensitivity or hypersensitivity be used.

Several studies have confirmed that infants can react to food antigens transmitted in their mother's breast milk (Cavagni, et al., 1988;

Fälth-Magnusson, 1989; Harris, Kolski, Campbell, Deuber, Marcus, & Douglas, 1989). It has been shown that infants who received only breast milk, developed allergies to food that their mothers had eaten. These infants may show signs of atopic dermatitis and may test positive to the suspected antigens.

In the author's experience, an allergic response to such common foods as tomatoes and cinnamon were misdiagnosed for over 10 years as a spastic colon. Drugs were given to decrease the spacticity without relief. After testing and diagnosis by an astute allergist, the foods were avoided and symptoms resolved within a week. The author is also aware of another case wherein a parent was told by the child's primary physician that there was no such thing as food allergies. The child had almost constant diarrhea and colic as an infant and toddler. An allergist diagnosed the child as having an allergy to milk. Soy was substituted in his diet for approximately four years. The parent realizing that substitution of a food can cause another allergic response, challenged the child with soy. He became severely depressed, and began crying after only a few hours, unable to cope well. He again avoided soy in his diet until he ate a small amount of margarine that contained soy. Within two hours he was again crying and unable to cope. Since that time he has been very careful about his food intake. His instructors both in music and school have noted an improvement in concentration and as a result his grades at school have improved.

The Problem

Since food allergies are still poorly defined, treatment is sporadic and often inadequate. Health professionals need to understand the importance of food allergies and their effects on the health of their clients if they are going to be able to care for them in a complete and thorough manner. Food allergies are not often recognized and legitimized by health care professionals, and tests are not as standardized or as accurate as needed. Asthmatic patients may have unrecognized food allergies which exacerbate their disease.

The immune mechanism in allergies and in food allergies specifically is poorly understood. Many diseases are only now being connected with an allergic response. Chronic intestinal problems may very well be connected with food allergies (Crowe & Perdue, 1992; Walker, 1987; Kniker, 1987). The frequency of fatal and near-fatal food-induced anaphylactic reaction has risen over the past several years (Sampson, Mendelson & Rosen, 1992). Food allergies evidence themselves in many ways. When clients present with various complaints it is important to elicit a diet history. If a person is obviously atopic it is even more imperative to elicit complaints of symptoms that could be tied to food allergies. Food allergies can cause a variety of symptoms. The increased allergic load on their system may cause an increase in airway reactivity. Clients do not always understand that the distress they are feeling may be caused by a common food they are eating, such as wheat, eggs or milk. Clinicians

also may not understand the important role that foods can play in a person's health. Professionals need to understand and recognize food allergies if they are going to treat effectively. Families need to be taught how to care for someone with food allergies to prevent serious reactions to food.

Purpose

The purpose of this study is to characterize the patient with asthma and to identify the role that food allergies play in asthma, that is, to determine whether or not food allergy reactions are related to severity of asthma.. Because of chronic inflammation of their airways, asthmatics exposed to food allergens may experience a severe allergic response. By identifying those patients at risk, it can be determined who may have more severe reactions requiring hospitalization or treatment in an emergency room or urgency care clinic. Professionals need to understand and treat food allergies and families need to be taught how to care for someone with food allergies to prevent serious reactions to food. Nurses and health care providers can contribute to the focused and comprehensive assessment of patients with asthma in relation to their food allergies and other diffuse clinical manifestations. They, therefore, can contribute to a more focused, comprehensive and successful management of the client's asthma and contribute to literature on nutrition as a legitimate part of treatment for asthmatics.

Chapter 2

Review of the Literature

In this section, the association between food allergies and asthma will be reviewed. A common thread in studies reviewed on food allergies is that asthma or other respiratory symptoms are common reactions. There is also a wide variation in numbers of responses to food allergies reported in the literature depending on the tests used to assess the food allergies and immediacy of the response the investigators examined.

In addition to asthma food allergy may also produce other atopic manifestations. In a study by Sampson (1987), 160 patients with atopic dermatitis were evaluated for food hypersensitivity. Subjects ranged in age from 3 months to 24 years. Of those patients studied, 47% had both allergic rhinitis and asthma and 4% had asthma without allergic rhinitis. Using skin prick tests first and double blind placebo controlled food challenge (DBPCFC) as a follow-up, 28% had respiratory symptoms including nasal congestion, rhinorrhea, sneezing, stridor, and/or wheezing. Food challenges were not conducted in 26 subjects because of a previous history of major anaphylactic reaction.

Onorato, Merland, Terral, Michel & Bousquet (1986) looked at 300 patients with asthma for IgE related food allergies. Each patient was given a questionnaire to determine food allergies. Those who responded negatively to the questionnaire were only given six prick tests for common food allergies of that geographical area. Those who

described a history of food intolerance or symptoms suggesting a food intolerance were given a set battery of food antigens by skin prick tests. Radioallergosorbent tests (RAST) were also performed on those with a positive history. If a test was positive, then DBPCFC was performed. Only 6% had positive preliminary tests and only 2.5% had asthmatic symptoms from the food challenges or history of anaphylaxis.

The number of foods and chemical additives to foods is so vast, the methodology that relies on a patient's awareness may not be sufficient. Considering nurses, physicians, and other health care providers are not always familiar with reactions caused by food hypersensitivity, a questionnaire may not elicit a history if people are unaware that a reaction that may have been affecting them or do not associate a symptom with a food they have eaten.

In another study, Novembre, de Martino, & Vierucci (1988) demonstrated food allergies in 11.4% of asthmatics using the prick test, RAST, and DBPCFC. Respiratory symptoms were present in 9.2% and 5.7% had immediate or delayed asthma. Their conclusions were: 1) that the numbers of persons with asthmatic reactions may have increased if non IgE-mediated reactions were counted, 2) food allergy induced respiratory symptoms almost always occur with other clinical manifestations such as gastrointestinal or cutaneous reactions, 3) many asthmatics who are sensitive to food allergens may not show symptoms until a cumulative level of allergens is reached 4) some foods may have a nonspecific role in bronchial reactivity, even when

there is no pathological explanation for the effect.

Sampson, Mendelson & Rosen (1992) reviewed records on 13 children and adolescents who had fatal or near-fatal anaphylactic reactions to food ingestion. Of the 13 (age range 2 to 17 years), 12 had asthma that was well controlled. The six patients who died reacted within 3 to 30 minutes after ingestion of the offending food. These foods included eggs, peanuts, other nuts and milk that are commonly found in prepared foods. They had eaten the offending foods without knowledge of their presence in the food they had ingested. Had the patients received immediate help when symptoms began, it is felt that they would not have had such severe reactions. Some of the children had not been tested for food allergies although many of them had had severe episodes previously.

In a study by Glasser (cited in Sampson, 1988) it was shown that infants, who received only breast milk from their mothers, could react to foods ingested by their mothers. These infants had atopic dermatitis and positive skin prick test to egg. When their mothers avoided eggs in their diet, the skin of their infants cleared. When eggs were reintroduced by the mothers in a controlled environment, each infant reacted with a rash within 4 to 36 hours. One infant began wheezing and had to be hospitalized.

There are many mediators that can cause hyperreactivity of the airways. Histamine is one of the major mediators and is released from eosinophils (Broide, et al., 1991; Podleski, 1988), basophils (Sampson,

Broadbent, & Bernhisel-Broadbent, 1989), and mast cells (Broide, et al, 1991). Sampson, Broadbent, & Bernhisel-Broadbent, (1989) studied 83 patients with the diagnosis of atopic dermatitis. Two-thirds also had asthma and allergic rhinitis. When subjects are exposed to a continual allergenic load there are many more histamine releasing cells that have rapid response to allergens. When subjects abstained from the foods that they were allergic to for approximately six months, the cell count decreased, the cells were slower to release their histamines and the person had little or no symptoms.

Using the double blind placebo controlled food challenge (DBPCFC) as the gold standard, Sampson and Albergo (1984) studied the accuracy of the prick tests, RAST, and DBPCFC on 40 children with atopic dermatitis. The standard acceptable tests for food allergies are skin prick tests, RAST, intradermal tests, and DBPCFC. The results showed that skin prick tests were more accurate than RASTs in predicting food allergies. Both the skin tests and the RAST were found to have excellent negative predictive accuracy (82% to 100%), but a poor positive predictive accuracy of 25% to 75% for skin tests, and 0% to 57% for RASTs. The RAST is more expensive, has a longer turn around time, but is the best test to use with dermographism or generalized dermatitis (Sampson & Albergo, 1984; Van Arsdel & Larson 1989). The RAST also cross reacts to environmental allergens such as grass when looking for grain allergies.

DBPCFC is now considered the diagnostic gold standard in food

allergy. There is a concern that DBPCFC cannot detect delayed reactions, particularly those involving asthmatics, (Chiaramonte & Altman, 1991). Furthermore false negative food challenges result if the amount of food ingested is smaller than the patient would normally consume. Additionally there is suspicion that some asthmatics may have increased nonspecific bronchial hyperreactivity without producing an actual episode.

In summary the studies of food allergies and asthma are often anecdotal and incomplete. A first step is to define the association between food allergies and asthma in a well -defined cohort of asthmatics as proposed in this study.

Conceptual Framework

The concept of reactivity is important in the management of food allergies and asthma. Both clients and health care providers need a better understanding of it. Reactivity is the response to a stimulus or prompting (American Heritage Electronic Dictionary, 1990). An increase in the load of environmental allergies can lead to an increase in symptoms of food allergies and exacerbate asthma (Dockhorn, 1987; Crowe, 1992). An increase in food allergen load can cause an increased response in the airways and increase episodes of asthma. Patients and providers react at various levels of intensity to these symptoms. If practitioners do not recognize the cause then they will treat only some of the symptoms and may look at food allergy as a totally unrelated phenomena.

An asthmatic's airways are reactive to many substances such as cold, exercise, inhaled allergens, and other allergens, including food, that enter the body in many ways. This study examines asthmatics who are primarily atopic. As each different allergen is added to the body of an atopic asthmatic, it causes the total allergic load to increase above a threshold. When the allergic load becomes too great for the immune system, then the asthmatic will have increased airway inflammation.

As the asthmatic's symptoms worsen, and the severity index becomes greater, there is a need for more medications which can include steroids. As the airways become more inflamed there is more wheezing both during the day and at night. The diameter of the airways become smaller leading to a decreased forced expiratory volume in one second (FEV_1) and decreased forced vital capacity (FVC). This increased reactivity may lead to increased hospital based care which includes visits to the urgency care clinic, emergency department, and ultimately hospitalization.

This conceptual framework is like a ladder with allergens represented as the rungs of the ladder, and the severity of asthma and hospital based care represent the legs of the ladder . If the asthmatic is at the bottom of the ladder then there are few symptoms, and little or no need for health care provider intervention. As the asthmatic is exposed to allergens such as food and environmental allergens the severity becomes greater and health care needs increase. If an asthmatic understands that certain foods are causing an increased load

and increasing the number of rungs on the ladder then they can eliminate those foods and decrease the rungs. During low environmental exposure, eating an offending food may keep them towards the bottom of the ladder and not cause many symptoms.

Research Hypotheses and Question

The hypotheses being explored in this study are:

1. Asthmatics who report food allergies have a more severe reactivity than asthmatics without reported food allergies as measured by the asthma severity index.

2.The type of food allergy reaction (systemic, respiratory, gastrointestinal, skin) predicts severity of asthma as measured by the asthma severity index

3. Asthmatics who report food allergies have an increase in hospital-based care (hospital admission, urgency care visits, emergency department visits) when compared to asthmatics without reported food allergies.

4a. Asthmatics who report food allergies and who exhibit positive responses to one or more of the skin prick tests of 13 allergens have a higher asthma severity index.

4b. Asthmatics who report food allergies and who exhibit positive responses to one or more of the skin prick tests of 13 allergens, have more hospital-based care than asthmatics without reported food allergies.

A research question generated for this study is:

What are the characteristics (age, gender, race, socio-economic status, family history) of asthmatics with reported food allergies that best predict severity of asthma and hospital based care?

Chapter 3

Methods

Design

This non experimental descriptive study will explore the hypotheses and question stated above. This study is part of a larger study entitled: "Predictors of hospital based care in asthma" by Molly Osborne, MD, PhD, principal investigator (PI) (1992). The larger longitudinal study of 800 asthmatic patients determines the factors that contribute to hospitalization and the severity of asthma.

The variables of the proposed study will include 400 asthmatic patients a subset of the participants include: the severity of asthma, the incidence of hospital based care, the number and type of food allergies, the reactivity to environmental allergies, the symptoms a participant manifests in relationship to ingesting certain foods, and the demographics of those with reported reactions to foods including race, age, gender, family history of atopy and asthma, and socio-economic status.

External validity is enhanced by the sampling design. The sample is composed of asthmatics from the health maintenance organization (HMO) and is stratified by age and gender. Participants may then self select to be included in the study. All socioeconomic groups are

represented. The age range of 3 to 54 was chosen since diagnostic accuracy is greatest in this age range. Overlap with bronchiolitis, emphysema, chronic bronchitis is minimized. Although the target population is all asthmatics with food allergies, certain tests can only be generalized to the Northwest. Allergen exposure changes in different parts of the United States and the world, therefore, the grass allergen extract would not be applicable to other segments of the country. The study is being conducted at the Lung Health Study facility, an off campus site of a large research university. The number of participants is adequate to generalize the study, per the power analysis calculated by Molly Osborne, MD PhD, PI for the original study (appendix E). Since long term predictors of hospital care is not a variable and because this is a subset of the original study, it was agreed that the power for this study is very strong

Sample

The sample consists of a subset of 400 asthmatics, ages 3 to 54, from a large health maintenance organization (HMO), living in a metropolitan area of the Northwest participating in the larger study. The stratified sample was generated from the facility's outpatient pharmacy records looking at dispensed asthma medications and from hospital admissions with the ICD9 admission code starting with '493' during the period 1/1/88 to 6/30/92. The population had to be eligible for HMO benefits on 6/30/92 and could not be currently participating in another study (appendix A). Recruitment is done by a letter notifying

eligible participants of the study (appendix B) and a follow-up phone call to recruit (appendix C). To qualify, subjects must have been told by a provider that they have asthma, must have had symptoms or use medication for the control of asthma over the last year, and must be members of the HMO at the time of recruitment. After a subject agrees to the study, a follow-up packet is sent. This includes a letter explaining the study and details regarding the medications the patient may use, for example how long to hold certain medications. A map and a consent form are also included (appendix D). The consent is brought in at the time of the testing, reviewed, and signed in the presence of the researcher.

Human Subjects

Human subjects are protected by confidentiality by process and records. All subjects are given a letter and number code which is then placed on the questionnaire to assure confidentiality. Researchers must sign a legal document insuring confidentiality and a conflict of interest statement. All study procedures have been approved by the Human Subjects Committees of the university and the HMO. Health care providers are not given patient information from the study. If there are any concerns regarding a participant's symptoms of asthma or a severely elevated blood pressure, the participant is notified by mail as soon as possible. If a participant gives permission for the PI to speak to the health care provider, then, under the discretion of the PI, that provider is informed.

Safety. Safety of the subjects is addressed throughout the study. The consent form outlines the possible hazards of the study which include a possible bruise or bleeding from the blood draw site, and slight swelling of the arm and possible reaction to the skin prick tests. Emergency medications, including oxygen and epinephrine, are located on site. No tests are performed without a second person available in the suite to call 911 in case of an emergency. All personnel are trained in emergency response, which includes CPR. Dr. Osborne is an advanced cardiac life support (ACLS) instructor and the author is a basic life support (BLS) instructor with a background in emergency department nursing.

Training. The four researchers spent a month training in the skills of the study. Those who did not have skill in blood drawing were taught at the blood draw lab at the university. Spirometry was taught by the spirometry lab at the university and practice sessions at the Lung Health Study facility. Skin prick testing was taught in the allergy department of the university by experts, under the direction of the chief physician, and practiced at the facility.

Data Collection

Process. The study consists of one 90 minute visit to the clinic. The clinic visit includes a questionnaire, a spirometry test assessing baseline and post bronchodilator airway function, a skin prick allergen test, including 13 environmental allergens and three controls, and collect a blood sample (which will only be analyzed for the larger study).

Correct use of an inhaler is assessed and a peak flow reading is obtained. If a child is under the age of six, the questionnaire is administered to the parents by phone because of the inability of the child to cooperate on the physical tests. Verbal consent is obtained from the parent.

Pilot. The study was piloted on children and adults prior to administration to current participants. For the pilot, blood was not drawn and minimal allergy tests were performed. All researchers participated in the testing of subjects and feedback on technique was given for uniformity in testing and interview skills, thus contributing to interrater reliability. Questions that were poorly understood or which needed revision were rewritten prior to testing on actual study participants.

Interview questionnaires. The questionnaires were constructed by the PI using several validated preexisting questionnaires and consultation with an expert allergist. There are two questionnaires (appendix F), one for children under the age of 15 and a corresponding adult questionnaire for those 15 and older. The hypotheses were adapted to focus on and include only those variables relevant to this study. The questionnaires include questions to determine severity of asthma, the most recent attack and the cause of that attack, allergy history including specific food allergies and family history, medication history including attitudes towards medications, health questions about both general and emotional health, demographics, socio-

economic status and occupation.

Spirometry. The spirometry machines are calibrated each day to the American Thoracic Society's specifications and the spirometry tests are performed within their specifications. After baseline spirometry, each participant is administered two puffs of isoproterenol by the researcher. A post bronchodilator spirometry test is then completed.

Allergy testing. The skin prick allergy tests are performed per protocols set by an expert allergist who trained all researchers in how to administer the tests. To insure interrater reliability and uniformity of administration the researchers applied positive controls and had obtained consistent results by six weeks after the start of the study. Positive antigens must measure at least 3mm. To insure reliability in measurement, all skin tests are measured by two trained research assistants from a hard copy of the wheal. The antigens used are alder, alternaria, aspergillis, histamine control, birch, cat, dog, grass mix, homodendron, juniper, two types of dust mite, penicillium, weed mix and two negative controls including a dry prick to control for carry over reactions from some of the more potent allergens.

Measurement and Analysis

Medications, foods, occupations, remedies, and health care providers are coded from a list and given a numerical value (appendix G). Spirometry tests will be assessed by programming using software designed by a programmer at the Lung Health Study. Allergy tests will be coded as either positive or negative. A positive will be at least one

reaction plus a positive histamine control. The severity of asthma index will be determined from preset variables such as symptoms, amount of medication, FEV_1 and FVC. Food allergies will be categorized first by presence or absence, then if present, by type of response: skin, respiratory, gastrointestinal and/or systemic reactions. Allergic responses to foods will also be categorized by the most common foods or families of foods. Also examined will be the percentage of asthmatics who report food allergies.

Analysis of the data will be conducted using standard descriptive statistical techniques. *T*-tests will be conducted to determine whether asthmatics with food allergies and a greater number of positive skin prick tests have a higher asthma severity index or increase in hospital based care than those without food allergies. Chi square tests will be conducted to determine: whether asthmatics with food allergies have more severe reactivity than asthmatice without food allergies; whether different categories of response to food allergies differ in relation to severity of asthma; and whether asthmatics with food allergies have increased hospital based care over asthmatics without food allergies. The presence of food allergies and demographic characteristics that best predict severity of asthma and hospital based care will be assessed using multiple regression analysis.

Potential for Utilization of Findings

This research will be valuable to nurses and health care providers in characterizing and understanding asthmatics with food allergies. The

results will allow nurses and health care providers to identify more accurately those clients more at risk of an asthma attack and who may require hospital based care. The better understood allergic reactivity is, the more competently nurses and health care providers can educate clients and provide a more holistic management to those clients with atopy and asthma. By achieving a better understanding, a client can effectuate a more capable management of the symptoms and resultant reactivity.

In a time of increased health care costs and a need for health care for everyone, it only makes sense to find ways to treat clients in a more holistic way. It is imperative to empower our clients to care for themselves in a more knowledgeable and healthy manner. If a client is able to understand what causes a chronic problem such as increased asthma symptoms, stomach pains, headaches or other symptoms, many will gladly give up the offending substance. The key is recognition and legitimation of the role of food allergies in asthma. Education must occur with nurses and other health care providers before a change in reactivity can begin with the client.

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IMPLICATIONS OF FOOD ALLERGIES IN THE SEVERITY OF ASTHMA

By

Nancy L. Emery, R.N., B.S.

Introduction

The role of food allergies in patients with asthma has not been well described.[1] Although food allergies might contribute to severity of asthma, the data are limited. Of interest, a recent article describes fatal and near-fatal anaphylactic reactions to food in children and adolescents, 92% of whom were asthmatic.[2]

A wide variety of upper and lower respiratory reactions including nasal, laryngeal, and pulmonary symptoms have been reported during double-blind, placebo-controlled food challenges.[3] To characterize sensitivity to food allergens in an asthmatic population, asthmatics were identified from automated pharmacy and hospitalization databases of a large Health Maintenance Organization (HMO), Kaiser Permanente (KP), Northwest (NW) Region, as part of an ongoing longitudinal study of people with asthma. The role that food allergies play in asthma was determined by cataloguing self-reported food allergies and relating prevalence of food allergies to severity of asthma and self-reported health care utilization.

The objective of this study was to evaluate the type of reactions and severity of reactions to food allergies in asthmatic patients. The purpose of this descriptive, non-experimental study was to determine if the presence of food allergies and/or skin test responsiveness are related to the severity of asthma and/or health care utilization.

Methods

Sample and Research Setting

Patients with medically diagnosed asthma were identified and characterized over a one year period as part of a longitudinal National Institutes of Health (NIH) cohort study to characterize risk factors for episodes of hospital-based care in asthma. The study enrolled subjects aged 3-55 years of age, stratified for age and gender. This age group was chosen because the diagnosis of asthma is least ambiguous during these years. These subjects were identified via automated pharmacy and hospitalization databases of a large Health Maintenance Organization, Kaiser Permanente (KP), NW Region. Subjects had at least two medications for asthma dispensed over the time period 1/1/88 through 6/30/92 and were KP members at the time of recruitment into the study. Kaiser Permanente NW is a large, federally qualified, group practice HMO that provides comprehensive, prepaid health care service to its members. The service area is centered in Portland, Oregon, and extends in a radius of about 50 miles. Kaiser Permanente currently provides coverage to about 20% of the Portland, Oregon population and the subscribers are known to be similar to the area population as a whole.[4,5]

The study was approved by the Human Subjects Committees of both the HMO and the university performing the study. All subjects, including the children participating in the study signed informed consents.

To characterize sensitivity to food allergens in this asthmatic population, 553 asthmatics were identified. A baseline evaluation included a questionnaire, skin testing, and spirometry. Information on self-reported food allergy was obtained in the questionnaire.

Questionnaires

The questionnaires were a composite consisting of relevant sections of: the American Thoracic Society-Division of Lung Disease 1978 respiratory symptom questionnaire; International Union Against Tuberculosis and Lung Disease bronchial symptoms questionnaire; RAND 36-item Health Survey; an asthma specific Quality of Life questionnaire; and questions relating to co-morbidity. Two questionnaires were developed and used, one for children 3-14 years and a corresponding questionnaire for those 15-55 years old. The questionnaires include data on demographic factors, patient characteristics such as tobacco use, atopy, pattern of medication use, self-reporting of compliance and adherence, behavioral characteristics, historical assessment of indoor air quality; characteristics of asthma such as duration of asthma, variation in asthma symptoms, and specialty of physician or provider.

Information on food allergy was obtained by asking the participant "Have you ever had a reaction caused by eating a particular food or foods". Respondents were asked about (1) independent documentation of food allergies, (2) hospitalization related to a food reaction, (3) types of foods causing symptoms (>100 were categorized), and (4) types of

allergic symptoms. There were 16 and 18 questions asked about specific symptoms for adults and children, respectively. Symptoms were categorized as respiratory, gastrointestinal, skin, and/or systemic.

Information on sulfite reactions was obtained by asking (child questionnaire) "Has your child ever had any difficulty with breathing after eating dried fruit?" or (adult questionnaire) "Have you ever had any difficulty with breathing after eating dried fruit, or drinking wine or beer?".

Parents of participants between the ages of three through five years were administered the questionnaire over the telephone. Children under age six were unable to perform spirometry correctly and skin tests were thought to be too traumatic. Therefore, the severity indexes or skin test scores could not be computed for these children.

Skin Testing

Thirteen skin prick tests, using allergens appropriate for the Pacific Northwest region, were applied using standard techniques. These allergens were alder, alternaria, aspergillus, birch, cat, dog, grass mix, homodendron, juniper, dust mite (dermatophagoides pteronyssinus and dermatophagoides farinae), penicillium, weed mix, and three controls (histamine, saline, and "dry" prick control). The technician carefully circled each wheal with an ink pen, placed cellotape over the mark, removed the tape, and placed it onto the data entry form. Two diameters were measured from the tape record: the widest diameter and the diameter at a right angle to the widest diameter. These

diameters were summed for each antigen.

Spirometry

Spirometry was performed using standardized methods with equipment that met or exceeded American Thoracic Society (ATS) requirements (Spirotech S-550 dry rolling seal spirometer using a digital shaft encoder with 10ml volume resolution).[6,7] The spirometry system uses software, developed by the NIH Lung Health Study, that determines the acceptability and reproducibility of each maneuver during the testing session and prompts the technician about possible problems such as slow initiation of the maneuver, early cessation of airflow, and coughing. The forced expiratory volume in one second (FEV_1) was reported as percent predicted FEV_1 calculated from the patient's actual performance in relation to predicted performance. Predicted values are based on age, height, and gender norms.[6,7]

Asthma Severity

We defined asthma severity according to National Asthma Expert Panel guidelines by creating a summed measure of respiratory symptoms, oral steroid use, and FEV_1.

Symptoms

1 < 1 daily or nocturnal symptoms weekly

2 2-6 days or nights with symptoms weekly

3 daily or nightly symptoms each day/night of the week

Medication Use

1 no oral steroid use

2 bursts of steroids less than half the time (<50% of time)

3 bursts of steroids more than half the time (>50% of time)

4 daily oral steroids

Spirometry

1 FEV_1, % > 80%

2 FEV_1, % 60-80%

3 FEV_1, % < 60%

Only those participants who participated in spirometry received an asthma severity score. For this analysis we dichotomized the score as mild = 3 - 5 and moderate - severe = 6 - 10.

Data Analysis

All analyses were performed using the SAS (Statistical Analysis System) statistical software package. Statistical methods included Pearson chi-square and Mantel-Haenszel trend chi-square tests for contingency tables, and logistic regression analysis to model asthma severity and hospitalizations.

Outcome Measures

Outcome measures included all episodes of self-reported hospital-based care. Hospital based care included only hospital admissions.

Results

Prevalence Of Food Allergies

Overall, 239 (43%) of participants reported adverse reactions to food. The prevalence of reported food allergies varied widely from 27% among 3-14 year olds to 48% among 15-34 year olds and 52% in 35-54 year olds (trend chi square=20.5, $p<.001$). Mean age was 32.2 ± 15.1 for those with reported food allergies and 25.3 ± 16.1 for those not reporting food allergies (t-test <.0001).

A significant increase in reported food allergies with increasing age ($p<0.0001$) is illustrated in Table 1. Females reported food allergies more commonly than males (38% males) $p<.001$). There was no trend in reported food allergies with respect to income or race. Of the 239 participants reporting food allergies, only 80 had further diagnostic testing done; 14/80 (17%) had RAST testing, 55/80 (69%) had skin prick testing, 21/80 (26%) had intradermal testing, and 9/80 (11%) had double-blind placebo controlled food challenge.

Types Of Foods Causing Adverse Reactions

The most common types of foods causing self-reported adverse reactions are listed in Table 2 according to the number of participants reporting adverse events. The top three foods causing adverse events were milk or dairy products, eggs, and peanuts. Although red wine was the second most frequent food reported to produce symptoms, it is unclear if this is a sulfite reaction or a reaction to some other ingredient in the wine. Sulfite reactions were reported by 22% of

participants. Food reactions were grouped into four categories: skin, respiratory, gastrointestinal, and systemic. These reactions were reported more commonly by adults than children (Table 3).

Relationship Of Food Allergy To Severity Of Asthma

Asthmatics who reported food allergies had more severe reactivity as measured by the asthma severity score than those who did not report food allergies. Furthermore, reported food allergies increased significantly with increasing severity of asthma ($p<.01$) and increasing age of participants ($p<.001$) (Table 4). While present for both genders, this trend was more pronounced and statistically significant only for females (Table 4). Further, this association appeared to exist only for allergies that were systemic in nature ($p<.04$). Irrespective of reported food allergies, there was no trend in severity with respect to income, nor with respect to family history.

Overall, the presence of food allergies was significantly associated with greater asthma severity (Odds ratio [OR]=1.6; $p=.02$). However, after adjusting for age and gender, food allergy was no longer significant (OR=1.2, $p=.41$). Both gender and age were significantly associated with asthma severity. A significant association was not found between food allergy and either gender or age.

Separate analyses indicated that food allergy was also not significant after adjusting for skin prick test responsiveness. Skin prick test responsiveness itself, however, was significantly associated with asthma severity among females, but not males, even after adjusting for

food allergies.

Relationship Of Food Allergy To Hospitalizations For Asthma

Participants with food allergies were more likely to report having ever been hospitalized for breathing problems ($p<.003$) than those without food allergies. This association was again strongest among females ($p=.011$). Treatment in an emergency room or hospitalization because of a reaction to food was reported by 30/239 (13%).

Relationship Of Food Allergy And Skin Sensitivity To Hospitalization

Overall, food allergy was significantly related to ever having been hospitalized ($p=0.003$; OR=1.8). Among females the odds ratio was 2.0 ($p=.01$), whereas among males the odds ratio was 1.5 ($p=.14$). These are all two tailed p values.

The results were qualitatively similar after adjusting for skin prick test responsiveness. Among females the odds ratio was 1.8 ($p=.05$) and among males the odds ratio was 1.3 ($p=.46$).

Discussion

This study demonstrated that, particularly in females, both severity of asthma and health care utilization are associated with self-reported food allergies and skin test responsiveness. Although these results demonstrate the importance of an area that many health care providers have not emphasized, the results are limited because the data are self-reported.

There are two limitations of self-reported data in this study. First, only 33% of these subjects had reported previous positive testing of food allergies. Second, it is difficult to determine whether or not the foods that the participants reported reacting to were the ones that caused the symptoms are what provoked the allergic reaction. That is, another agent, even an additive, might be the cause of the reaction rather than the food reported by a participant. This necessitates the use of controlled food challenges.

Reports on the validity of self-reported health care utilization versus chart-confirmed health care utilization are limited. Studies conducted by the National Center for Health Statistics suggest that about 70% of asthma encounters documented in the medical record are typically captured by self report. However, these same studies also indicate a significant number of self reported encounters that are not captured in the medical record. The reason for the latter discrepancy is not fully understood.[9]

Only the self-reported systemic allergic reactions to foods were

associated with severity of asthma and health care utilization (i.e. headache, swollen tongue, throat closing off, dizziness, loss of consciousness). Of interest, the recent study by Sampson et al.[2] demonstrated fatal and near-fatal anaphylactic reactions to food in children and adolescents, the majority of whom were asthmatic (12/13 = 92%).

Many studies only address respiratory, gastrointestinal, and dermatologic reactions,[10-15] which do not correlate with severity of asthma in this study. Most earlier studies investigation of the pathogenic role of food hypersensitivity in chronic asthma had suggested that food-induced bronchospasm was uncommon, occurring in less than 10% of asthmatics.[1,15] In one study, asthmatic patients followed in a pulmonary clinic were screened by clinical histories, skin testing, radioallergosorbent (RAST) analyses, and double blind placebo controlled food challenges (DBPCFC).[1] Of 140 asthmatic children evaluated, only 8 (5.7%) had documented positive oral food challenges, including wheezing. The authors concluded that food-induced, IgE-mediated respiratory reactions and asthma are rare and frequently associated with other findings such as atopic dermatitis.

Also, incidence and severity of respiratory symptoms can be much greater than documented bronchospasm in DBPCFC trials. For example, a recent article by James et al.[3] demonstrated that respiratory symptoms were common in children with atopic dermatitis and food hypersensitivity undergoing DBPCFC, and wheezing was provoked in

almost 20% of these children. Significant objective changes in pulmonary function, however, were rare as a result of food-induced allergic reactions.[3]

Further, research on the association between food allergy and symptoms is warranted based on findings reported here. A larger study with food challenge and appropriate skin testing of asthmatics is necessary to confirm these results Identifying relevant food allergens and eliminating them from the diet may help improve respiratory disease.[3] By identifying those patients at risk, it can be determined who may have more severe reactions requiring closer health care management. This study suggests that asthmatics who give a history of systemic symptoms to foods should be managed as high risk patients by health care providers. This management might include aggressive education and medical management, use of peak flow meters to objectively measure lung function, and a plan for rapid treatment of systemic symptoms should they arise.

Table 1 Characteristics of Sample with Food Allergies

	Food Allergies		
	Yes	No	Sig.
n	239	314	
Age			
3-14	45 (19%)	122 (39%)	
15-34	68 (29%)	74 (24%)	
35-55	126 (52%)	118 (38%)	p<.001[1]
Gender			
Female	147 (62%)	135 (43%)	
Male	92 (38%)	179 (57%)	p<.001[2]
Household Income			
<$20,000	19 (8%)	29 (9%)	
$20-39,000	74 (31%)	111 (35%)	
$40-69,999	111 (46%)	135 (43%)	
>$70,000	35 (15%)	39 (12%)	p=.14[1]
Race			
White	212 (88%)	291 (93%)	
Other	28 (12%)	23 (7%)	p=.11[2]

[1] two-tailed significance level based on Mantel-Haenszel chi-square statistic

[2] two-tailed significance level based on corrected chi-square statistic

Table 2. Types of Foods to Which Participants Commonly Reported Adverse Reactions

Type of Food	All Participants	Participants with Food Allergies
n	553	239
Milk/dairy	14.1%	32.6%
Red Wine	3.8%	8.8%
Peanuts	3.3%	7.5%
Eggs	3.3%	7.5%
Apples	2.9%	6.7%
Chocolate	2.9%	6.7%
Walnuts	2.7%	6.3%
Oranges	2.5%	5.8%
Strawberries	2.4%	5.4%
Bananas	2.2%	5.0%
Melons	2.2%	5.0%

Table 3 Proportion of Food Allergy Positive Subjects Reporting Various Types of Adverse Reactions to Foods

	Age Group	
Type of reaction[1]	3-14 yrs	15-55 yrs
(n)	45	194
Systemic	40%	59%
Skin	67%	42%
Gastrointestinal	62%	43%
Respiratory	64%	69%

[1] Categories not mutually exclusive

Table 4 Proportion of Subjects With Moderate to Severe Asthma By Age, Gender, and Reported Food Allergies

	Reported Food Allergy	
	Yes	No
Age		
3-14 yrs	18% (6/34)	15% (14/93)
15-34 yrs	29% (20/68)	20% (15/74)
35-55 yrs	46% (58/125)	42% (49/117)
Cender		
female	44% (61/138)	34% (42/125)
male	26% (23/89)	23% (36/159)

Table 5 Proportion of Subjects Ever Hospitalized by Gender and Reported Food Allergies

	Reported Food Allergy	
Gender	Yes	No
Females	33% (48/147)	19% (26/135)
Males	29% (27/92)	21% (38/179)

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Abbreviations

Health Maintenance Organization (HMO)

Kaiser Permanente (KP)

North West (NW)

National Institutes of Health (NIH)

American Thoracic Society (ATS)

forced expiratory volume in one second (FEV_1)

Statistical Analysis System (SAS)

APPENDIX A

Population Memo

Definition of ASH Populaition

03/05/93

We begin with the Kaiser Permenete outpatient pharmacy dispensings from 01/01/88 to 06/30/92 and search for only the dispensings that pertain to asthma. From these dispensings we find all the people who had two or more drug dispensings and who were between the ages of 3 to 54 on 01/01/93 and who were eligable for Kaiser benefits on 06/30/92 and who are not currently selected to participate in another CHR study.

Now we turn to the Kaiser Permenete hospital admissions from 01/01/88 to 06/30/92 and search for only the admissions with the primary ICD-9 admit code starting with '493'. From these admissions we find all the people who were between the ages of 3 to 54 on 01/01/93 and who were eligable for Kaiser benefits on 06/30/92 and who are not currently selected to participate in another CHR study.

We then take the selected outpatient group and divide them into 5 levels based on the date of there last drug dispensing.

Last Dispense Date Between	Level
07/01/91 - 06/30/92	1
07/01/90 - 06/30/91	2
07/01/89 - 06/30/90	3
07/01/88 - 06/30/89	4
01/01/88 - 06/30/88	5

We then take the selected inpatient group and randomly assign a date in the level 1 range. The combination of the outpatient and inpatient groups define the population for the ASH study.

The ASH population is then divided into 6 cells defined as:

Sex	Age Range		
M	3-14	15-34	35-54
F	3-14	15-34	35-54

For the purposes of recruitment we fill the cells starting with Level 1 and work our way down through Level 5.

APPENDIX B

Recruitment Letter

KAISER PERMANENTE

Dear Kaiser Member,

The Kaiser Permanente Center for Health Research and the Oregon Health Sciences University are conducting a joint research study of asthma in the Portland area. Funding for this comes from the National Institutes of Health.

Respiratory diseases such as asthma cause great distress to many people and are of particular concern in children. We are trying to find out more about the characteristics of asthma and would like your help in doing so.

If a doctor has told you that you have asthma AND you have had symptoms or have taken medication for asthma in the last year, we would like to invite you to take part in a voluntary respiratory health evaluation as part of the study. Because the Lung Health Study Clinic has the special facilities needed to conduct this evaluation we have arranged for a clinic staff person to call you. The study will be conducted at the Lung Health Study Clinic which is located in Southwest Portland under the Ross Island Bridge.

If you prefer not to wait for our call you are welcome to call us directly at 494-8647 and ask for the "Kaiser Asthma Survey". We regret that we are not able to offer this screening to everyone.

Your participation is important to us! Should you have any questions about the study, please contact one of us.

Sincerely,

William M. Vollmer

Molly L. Osborne

William M. Vollmer, Ph.D
Co-Principal Investigator
Kaiser Permanente Center for
Health Research
(503) 335-6755

Molly L. Osborne, M.D. Ph.D
Co-Principal Investigator
Oregon Health Sciences University
(503) 494-8647

APPENDIX C

Recruitment Phone Script

(Telephone Recruitment Script)

May I speak to (participant's name).

Hello (participant's name). This is _____ from the Lung Healt
Study. Recently, you received a letter about our study of peopl
with asthma. I'd like to ask if you would be willing to participat
in this joint research study between OHSU and the Kaiser Permanent
Center for Health Research if indeed you do have asthma. You have
been chosen because you may have asthma. The PURPOSE of the study
is to learn more about the characteristics of asthma.

Has a doctor ever told you that you have asthma? [Y/N ASTHMA]
[YES] can I also ask

1. if you have ever been told by a health professional that you have chronic bronchitis, emphysema, smoker's lung, or chronic obstructive lung disease? [Y/N COPD]
2. Do you have current SYMPTOMS (within the LAST 12 MONTHS) of asthma? Symptoms might include wheezing or cough or intermittent episodes of shortness of breath. [Y/N] *

[NO] It looks like you won't be eligible for this study. However, before I let you go, can I also ask

1. if you have ever been told by a health professional that you have chronic bronchitis, emphysema, smoker's lung, or chronic obstructive lung disease? [Y/N COPD]
2. Do you have current SYMPTOMS (within the LAST 12 MONTHS) of asthma? Symptoms might include wheezing or cough or intermittent episodes of shortness of breath. [Y/N]

**To be ELIGIBLE for this study you have to:

1. Have been told by a doctor that you have asthma.
2. Be a member of Kaiser Permanente.
3. Have asthma currently.
*. If you DON'T have symptoms have you been on medication for asthma within the last year? [Y/N]

[IF YES to all 3 - ELIGIBLE FOR STUDY....]
The study consists of a baseline visit of 90 minutes and four follow-up telephone calls, one every six months over a two year period. The baseline clinical appointment for the study is a one time appointment. It will include testing your skin sensitivity to various allergens such as cats, mites, and molds, and testing your lung function by measuring air moving in and out of your lungs. We will be glad to give you the results of both these tests. We will also ask you questions about your asthma and take a small sample of blood. The study will be conducted at the Lung Health Study Clinic which is located in SW Portland under the Ross Island Bridge. Are you interested in participating in this study? [If NO, thank participant and conclude conversation]. Although the information is very important for research purposes WE ARE SORRY BUT IT IS UNLIKELY TO HAVE ANY EFFECT ON THE CLINICAL MANAGEMENT OF YOUR ASTHMA.

We would be glad to schedule you Monday through Friday between 8am and 8pm at your convenience, and some Saturdays are also available. What would work best for your schedule?

MEDICATIONS: Are you currently taking any asthma medications? [YES] Which one(s)? [list meds on appt reminder packet sheet]
PLEASE BRING ALL YOUR MEDICATIONS OR A LIST OF ALL YOUR MEDICATIONS TO THE CLINIC VISIT

We would like you to WITHHOLD your (medication) before undergoing the baseline evaluation. Specifically, to withhold:

* INHALED BETA AGONISTs for up to 8 hr;
  INHALED/INTRANASAL STEROIDS for up to 12 hr
  INHALED ATROVENT for up to 12 hr
  INHALED INTAL for up to 24 hr
* beta-agonist syrups, tablets, injections
  SHORT ACTING up to 12 hr
  LONG ACTING up to 18 hr
* theophylline preparations
  SHORT ACTING for up to 24 hr
  LONG-ACTING for up to 48 hr
* STEROID tablets for 24 hr
* ANTI-HISTAMINES: SHORT ACTING for 24 hr
  LONG ACTING anti-histamines for up to 3 days, using SHORT-ACTING over-the-counter anti-histamines until 6 hours before the evaluation.

** PLEASE HOLD CAFFEINATED BEVERAGES 8 HOURS**

However, if you experience difficulty breathing while off medication, it is certainly appropriate to take your medications. PLEASE TAKE your medication, call us and we will reschedule your appointment. If you are unable to hold medications A SECOND TIME, please take the medication no later than AN HOUR beforehand, and keep your appointment. Please keep a record of any medication that you do need to take.

I will mail you an appointment reminder card which will indicate when to take your last dose of (med) before your appointment. If you have any questions or concerns, feel free to call a staff person here anytime before your visit. The phone number will be on the card. Do you have any questions?

I will be sending you a packet in the mail that will contain the appointment reminder card, a map showing the location of the Lung Health Study clinic, and a consent form for you to review. Please don't sign the consent form before your visit. At the time of your appointment you will have an opportunity to discuss any questions you may have with a staff member before you sign this form and begin your visit.

May I verify your address? (VERIFY ADDRESS) BECAUSE TWO OF US WILL BE HERE ESPECIALLY FOR YOUR VISIT, IT IS VERY IMPORTANT THAT YOU KEEP THIS APPOINTMENT OR TRY TO GIVE US AS MUCH NOTICE AS POSSIBLE, SUCH AS 48 HOURS, IF YOU NEED TO RESCHEDULE.

Do you have any questions? THANK YOU so much for participating. We're looking forward to seeing you here at the Lung Health Study Clinic on (date and time).

APPENDIX D

Participant Packet

OREGON HEALTH
SCIENCES UNIVERSITY
Lung Health Study

Dear _____,

Thank you for agreeing to participate in the Asthma Survey which is being conducted in Portland, Oregon cooperatively by the Oregon Health Sciences University and Kaiser Permanente Center for Health Research. Your participation will help add to medical knowledge and your willingness to participate is very much appreciated.

At your visit to the Lung Health Study clinic you will be asked some questions about your general health, your asthma, smoking patterns, your work, your home and your family. You wil also be asked to participate in some tests. Your blood pressure, weight and height will be measured in addition to the following tests.

Blood sample to test for allergy
A small amount of blood will be drawn in the standard way from a vein in your arm.

Skin tests for allergy
Skin tests are performed by pricking the skin on the inner surface of your arm or your back. If you are allergic, a small red mark may appear and you may itch for a short time. The technician will measure the size of the mark after about 15-20 minutes.

Breathing tests
Your lung function will be tested to see how much air is in your lungs and how much you can blow out quickly. You may be asked to do this several times. You will then be given two puffs of a bronchodilating medication and have your lungs tested again.

On the back of this letter you will find your appointment reminder and some simple guidelines we would like you to follow prior to your visit. Feel free to call the Lung Health Study clinic at (503)494-8647 if you have any questions or if you need to reschedule. Thank you again for your participation.

Sincerely,

William M. Vollmer

Molly L. Osborne

William M. Vollmer, Ph.D.
Co-Principal Investigator
Kaiser Permanente Center
for Health Research

Molly L. Osborne, M.D.,Ph.D.
Co-Principal Investigator
Oregon Health Sciences University
(503)494-8647

KAISER ASTHMA SURVEY
APPOINTMENT REMINDER NOTICE

OHSU Lung Health Study Clinic, 3030 S.W. Moody, Suite 105
Portland, OR 97201
Phone: (503)494-8647

Appointment Date: _____

Appointment Time: _____

*** Because of the special preparations for your visit, please try to keep this appointment. Please give us as much notice as possible if you need to reschedule.**

This appointment should last approximately 90 minutes.

Prior to your appointment please use the following guidelines for taking the following medications:

Take Last Dose of _____ by _____

Take Last Dose of _____ by _____

Take Last Dose of _____ by _____

Take Last Dose of _____ by _____

*** Please remember to bring all of your medications (or a list of them) with you to your appointment.**

***If you smoke,** please do not smoke for one hour before coming to the clinic.

*****Please do not eat or drink any caffeinated food or beverages for 8 hours prior to your appointment (coffee, tea, colas, cocoa, chocolate).

*****If you have a **chest cold, influenza, chronic bronchitis or sinus infection** during the week prior to your appointment, please call to reschedule the appointment.

*****Please do not have a large meal immediately before your visit to the clinic.

QUESTIONS? Call the Kaiser Asthma Survey at (503)494-8647.

DIRECTIONS TO THE LUNG HEALTH STUDY

Appointment Date _____

Appointment Time _____

The Lung Health Study is located in the Westwood Corporation Building, 3030 S.W. Moody, Suite 105, Portland, Oregon 97201 (503) 494-8267

(Please be patient--the building may be difficult to find at first.)

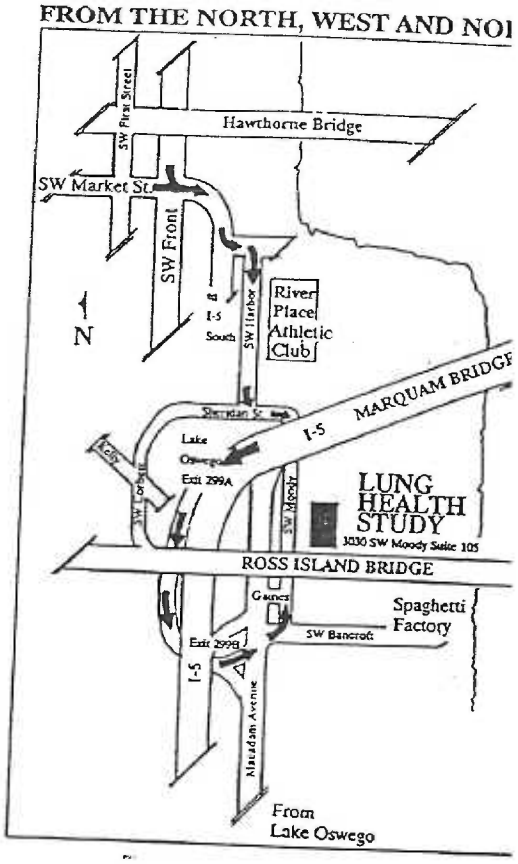
From the North or Northeast (I-5 South/I-84 West)
After coming off the west side of the Marquam Bridge, take the Lake Oswego exit (Exit 299A) and proceed approximately 1/4 mile to the I-5 underpass at Bancroft. As you come under the overpass, be sure to keep in the left lane at the intersection then go across Macadam Avenue onto Bancroft (towards the Spaghetti Factory). Just as you cross the railroad tracks, turn left on Moody and proceed about 1/4 mile north. The Westwood is a brick building located on the right hand side of the street just north of and under the Ross Island bridge.

From the West
From eastbound Hwy-26/Sunset highway, take City Center exit and proceed down Market Street to Front Avenue. Continue across Front and follow curve of road then turn left at first signal as if going to the River Place Athletic Club. Then turn right (south) onto Harbor (the two-lane street just before the athletic club) and continue about 1/4 mile. Make a left turn at end of street onto Sheridan and follow right hand curve onto Moody St. The Westwood is a brick building located about 1/4 mile from this point on the left hand side of the street just north of the Ross Island bridge.

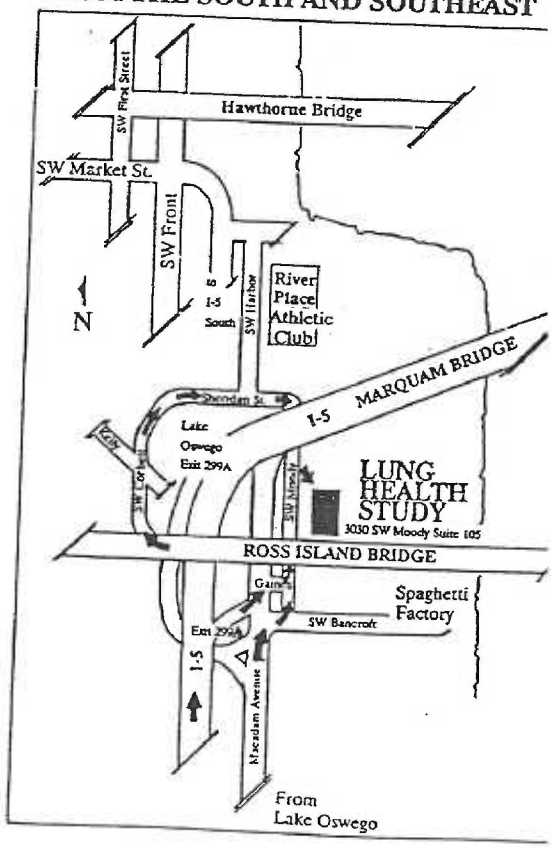
From the Southeast (using the Ross Island Bridge)
Bear right just after crossing the Ross Island bridge and follow the sign to Corbett St. Proceed across Kelly and down the hill. Corbett will intersect with Sheridan at the bottom of the hill. Sheridan turns right at Moody St. The Westwood is a brick building located about 1/4 mile from this point on the left hand side of the street just north of the Ross Island bridge.

From the South
Proceed north on I-5 to the Macadam Avenue exit (Exit 299A). Continue 1 block to Gaines St. (just past the Public Storage sign), turn right and proceed down the hill for 1 block. Turn left at the railroad tracks onto Moody then proceed about 3 blocks. The Westwood is a brick building located on the right hand side of the street just north of the Ross Island bridge.

FROM THE NORTH, WEST AND NOI



FROM THE SOUTH AND SOUTHEAST



Oregon Health Sciences University
Kaiser Permanente, Northwest Regior

Asthma Survey Consent Form
(Adult)

Principal Investigator: Dr. Molly Osborne (503) 494-8267

The Asthma Survey is a joint study being conducted by the Oregon Health Sciences University and Kaiser Permanente Center for Health Research. Funding for the study comes in part from the National Institutes of Health.

Purpose

The purpose of the research study is to determine how common respiratory symptoms and diseases are in asthmatics, and to find out what factors may be linked to the development of respiratory problems.

Procedures

The study consists of a clinic appointment of an hour and a half and four follow-up telephone calls over a two year period, one call every six months. I understand that the follow-up telephone calls will ask about how I am doing with my asthma and will only take a few minutes.

My participation will initially require about 90 minutes of my time and will be held at the Oregon Health Sciences University's Lung Health Study center. I will be asked to answer a series of questions and will perform the following measurements and tests.

1. The questionnaire will include questions about my general health, education, employment history, smoking patterns, and where I live.

2. Breathing Tests:

    a. I will be asked to perform simple breathing tests that involve blowing hard into a machine called a spirometer.

    b. I will be given two puffs of a bronchodilating medication to open my airways and my lungs will be tested again on the spirometer.

3. A physician, nurse or technician will prick the skin on my arm or back about fourteen times to determine if I am sensitive to a variety of common environmental agents (allergens). These tests will include the following allergens: cat, mites, molds, grasses, trees, and a histamine control. These tests are commonly done by allergists and other doctors. I will know the results of these tests in about 15 minutes.

4. A technician will draw about four teaspoons of blood from my arm.

5. My blood pressure, weight, and height will be measured.

Risks

I understand that these tests may involve some discomfort and potential risk as discussed below The blood drawing may cause slight discomfort and carries a small risk of bleeding and/o bruising at the puncture site.

The skin prick tests may cause itching, stinging, or slight discomfort at the site. This usuall does not last long and can be relieved by antihistamine cream that will be available. A very few participants may experience dizziness or nausea. There is also a very slight risk of a serious allergic reaction from the skin tests. This can be readily reversed by an injectable medicine that will be immediately available.

I may also be asked to delay taking certain breathing medications on the day of my tests, and I understand that this may cause some discomfort with my breathing. The length of time that I would have to delay taking these medications will depend on the time of my clinic appointment and the type of medication I am using specific guidelines are in the reminder packet. However, if I experience difficulty breathing, it is okay to take my medications.

Benefits

I will also receive certain benefits from participating in the study. Specifically, I will receive information about my lung function and my sensitivity to common allergens. In addition, I will be making a contribution to science. However, there is no direct benefit to me for participation in this study.

Confidentiality

I understand that all of my results will be kept strictly confidential, and that neither my name nor other identifying information will be used in any reports or study publications.

Costs

I understand that I will not be charged for any of the tests, and that I will not be reimbursed for my participation in the study.

Liability (Kaiser Permanente)

Should I incur any physical injury determined by physicians of Kaiser Permanente to result from my participation in this study, all resulting medical care and hospitalization will be provided free of charge in Kaiser Permanente facilities.

Liability (Oregon Health Sciences University)

Should I establish that any injury that I sustain in this research project is the fault of the University, its officers or employees, compensation will be available to me under the terms of and subject to the State Liability Fund.

Rights as a Research Subject

If I have any questions about my rights as a research subject, I may contact the Oregon Healt Sciences University Institutional Review Board at (503) 494-7887.

If I have any questions about this research, my rights and responsibilities as a research subject or about research-related injuries, I may contact M.R. Greenlick, Ph.D., Vice-President fo Research, Kaiser Foundation Hospitals, 335-2400.

Questions about Research Project

If I have any questions about the asthma survey, I may contact Dr. Molly Osborne at (503) 494-8267.

Finally, I understand that participation in this study is voluntary and that I am free to withdraw from participation at any time. I also understand that if I do decide not to participate it will in no way affect my medical care or Health Plan membership or that of any other member of my family. I or the person signing the consent form will receive a copy.

_____ _____

Signature of Participant Date

_____ _____

Signature of Witness Date

MO:rk...\consent.frm
KP CPHS Approved
approved 10/21/92
revised 2/1/93
ORS# 2832

Oregon Health Sciences University
Kaiser Permanente, Northwest Regior

Asthma Survey Parental Consent Form
(Pediatric)

Principal Investigator: Dr. Molly Osborne (503) 494-8267

The Asthma Survey is a joint study being conducted by the Oregon Health Sciences University and Kaiser Permanente Center for Health Research. Funding for the study comes in part from the National Institutes of Health.

Purpose

The purpose of the research study is to determine how common respiratory symptoms and diseases are in asthmatics, and to find out what factors may be linked to the development of respiratory problems.

Procedures

The study consists of a clinic appointment of an hour and a half and four follow-up telephone calls over a two year period, one call every six months. I understand that the follow-up telephone calls will ask about how my child is doing with his/her asthma and will only take a few minutes.

My child's participation will initially require about 90 minutes of his/her time and will be held at the Oregon Health Sciences University's Lung Health Study center. My child will be asked to answer a series of questions and will perform the following measurements and tests.

1. The questionnaire will include questions about my child's general health, education, employment history, smoking patterns, and where he/she lives.

2. Breathing Tests:

    a. My child will be asked to perform simple breathing tests that involve blowing hard into a machine called a spirometer.

    b. My child will be given two puffs of a bronchodilating medication to open the airways and his/her lungs will be tested again on the spirometer.

3. A physician, nurse or technician will prick the skin on my child's arm or back about fourteen times to determine if he/she is sensitive to a variety of common environmental agents (allergens). These tests will include the following allergens: cat, mites, molds, grasses, trees, and a histamine control. These tests are commonly done by allergists and other doctors. I will know the results of these tests in about 15 minutes.

4. A technician will draw about four teaspoons of blood from my child's arm.

5. My child's blood pressure, weight, and height will be measured.

Risks

My child and I understand that these tests may involve some discomfort and potential risk as discussed below. The blood drawing may cause slight discomfort and carries a small risk of bleeding and/or bruising at the puncture site.

The skin prick tests may cause itching, stinging, or slight discomfort at the site. This usually does not last long and can be relieved by antihistamine cream that will be available. A very few participants may experience dizziness or nausea. There is also a very slight risk of a serious allergic reaction from the skin tests. This can be readily reversed by an injectable medicine that will be immediately available.

My child may also be asked to delay taking certain breathing medications on the day of his/her tests, and my child understands that this may cause some discomfort with his/her breathing. The length of time that my child would have to delay taking these medications will depend on the time of his/her clinic appointment and the type of medication my child is using specific guidelines are in the reminder packet. However, if my child experiences difficulty breathing, it is okay to take his/her medications.

Benefits

My child will also receive certain benefits from participating in the study. Specifically, my child will receive information about his/her lung function and his/her sensitivity to common allergens. In addition, my child will be making a contribution to science. However, there is no direct benefit to him/her for participation in this study.

Confidentiality

I understand that all of my child's results will be kept strictly confidential, and that neither his/her name nor other identifying information will be used in any reports or study publications.

Costs

I understand that I will not be charged for any of the tests, and that my child will not be reimbursed for his/her participation in the study.

Liability (Kaiser Permanente)

Should my child incur any physical injury determined by physicians of Kaiser Permanente to result from his/her participation in this study, all resulting medical care and hospitalization will be provided free of charge in Kaiser Permanente facilities.

Liability (Oregon Health Sciences University)

Should my child establish that any injury that he/she sustains in this research project is the fault of the University, its officers or employees, compensation will be available to him/her under the terms of and subject to the State Liability Fund.

Rights as a Research Subject

If my child or I have any questions about his/her rights as a research subject, I may contact the Oregon Health Sciences University Institutional Review Board at (503) 494-7887.

If I have any questions about this research, my rights and responsibilities as a research subject, or about research-related injuries, I may contact M.R. Greenlick, Ph.D., Vice-President for Research, Kaiser Foundation Hospitals, 335-2400.

Questions about Research Project

If my child or I have any questions about the asthma survey, I may contact Dr. Molly Osborne at (503)494-8267.

MO:rk...\consent.chd
KP CPHS Approved
approved 10/21/92
revised 2/1/93
ORS# 2832

Finally, I understand that participation in this study is voluntary and that my child is free to withdraw from participation at any time. I also understand that if I do decide not to participate it will in no way affect my medical care or Health Plan membership or that of any other member of my family. I or the person signing the consent form will receive a copy.

Signature of Participant	Date
Signature of Parent or Guardian *(if participant is a minor)*	Date
Signature of Witness	Date

Oregon Health Sciences University
Kaiser Permanente, Northwest Region

Child's Assent for Asthma Survey

Principal Investigator: Dr. Molly Osborne (503) 494-8267

I agree to be in an asthma survey. It is OK to have several things happen. I will answer some questions, and blow out through a breathing machine before and after breathing something that will open up my airways. I will also have my skin pricked several times which may cause some itching or stinging or slight discomfort. If that happens, some cream will be put on my skin to make it feel better. I will also have a few teaspoons of my blood drawn, which may also be uncomfortable, and I know there is a small chance of a bruise or bleeding.

_____ _____

DATE Signature of Child

I have reviewed the contents of the INFORMED CONSENT with _____ (participant) at a level appropriate to his/her understanding, and I feel he/she understands these matters and their implications.

_____ _____

DATE Signature of Asthma Survey Staff Member

APPENDIX E

Power Calculation

As noted above we will divide subjects into risk deciles based on the best fitting model and co a general goodness-of-fit statistic for the target population and for the validation sample. The la will be a randomly selected subset (n=200) of the original sample and will not be used in the n building. Validation will be performed using the approach of Lemeshow et. al. [77] as illustrat Higgins et. al. [52].

We recognize that some people will have multiple events over the study period. As a secondary of analysis, repeaters will be separated from non-repeaters. Then we will determine whether or the distribution across risk deciles of predictor variables differs between repeaters and non-repe

Sample Size

Power calculations for the proposed study are presented below. The calculations are presented f sample size of 800 and assumes that 200 of these subjects are reserved for the validation sampl Because our design does not fall in the classical hypothesis testing framework and because of t large number of predictor variables that will be available, we have adopted a more generic appr Specifically, the tables address the power to detect a given relative risk (1.25, 1.50, 2.00) for ar arbitrary, dichotomized predictor variable. We further assume that the "at risk" proportion of th population varies between 10% and 50%. As the tables show, our sample sizes will be inadequ identify predictor variables with relative risks of 1.25 or less, and will be more than adequate t detect relative risks of 2.0 or greater. The power is generally adequate (>75%) for detecting rel risks of 1.50. These results should only be viewed as approximate since they treat all predictor variables as dichotomous and do not account for correlations among the predictor variables.

All calculations below assume a type I error rate of 5% with a two-tailed alternative hypothesis overall event probability is P and number of subjects is N. n_a/N is the proportion of subjects in group "a" and RR is the relative risk for group "a" relative to group "b". The overall event probabilities are derived from the data presented in Pilot Data, Section C. They assume a value 0.31 as the most likely outcome, but include a minimum of 0.25 and a maximum of 0.38.

Table 2. Power Calculations Assuming N=600.

			(n_a/N)			
Overall event probability	RR "a"vs"b"	0.1	0.2	0.3	0.4	0.5
0.31	1.25	21%	28%	36%	41%	42%
	1.50	60%	85%	87%	90%	92%
	2.00	99%	100%	100%	100%	100%
0.25	1.50		65%		76%	
0.31	1.50		85%		90%	
0.38	1.50		91%		97%	

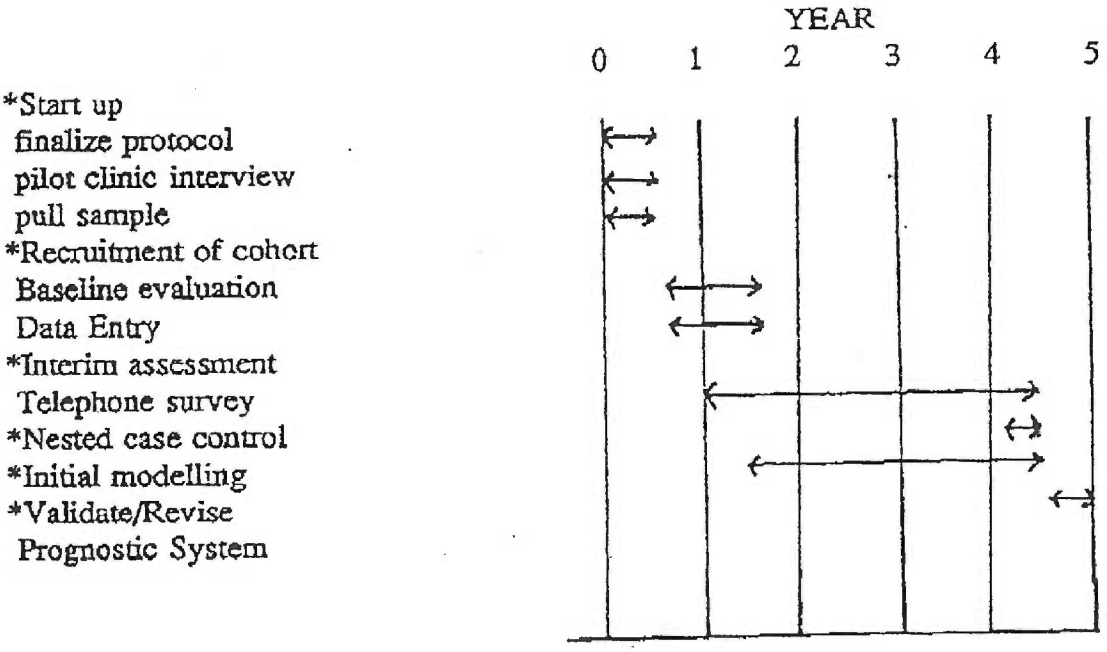
As a specific example, if abnormal lung function, as measured by FEV1, increases the risk of hospital-based episodes of health care in patients with asthma, the relative risk will be >1.0. Sir approximately 39% of patients with asthma have an abnormal FEV1 [78], there is a >90% char detecting a relative risk of 1.50. There is a 100% chance of detecting a relative risk of 2.00.

Conclusion

In conclusion, these studies are timely and they deal with the important clinical problem of identifying modifiable risk factors for hospital-based care for patients with asthma. I have been working for several years with my co-investigators who have extensive experience in epidemiol and I have just completed training in Biostatistics and Epidemiology at McGill University so th am ready to be a principal investigator on this project. Identification of modifiable risk factors hospital-based care will allow physicians to improve the quality of life for patients with asthma also reduce health care costs.

Timeline

I will be able to finalize the protocol, pilot the clinic interview and pull the sample from the T database within six months of funding. The survey will be performed over a three year period follow-up by telephone interview every four months. The nested case-control study will be run completion of the survey period. Data analysis will be completed in year five. The entire proje expected to last five years.



APPENDIX F

Questionnaires

PEDIATRIC

2/23/93

1. How do you feel without your medications? ..... quite symptomatic ☐
   (If symptomatic, perform spirometry & give medications) okay ☐

2. Check that address and telephone number are correct (additional telephone for follow-up if necessary) _____

3. Social security number:

4. What medications are you currently taking (include over-the-counter)

Name (generic)	Dose	Frequency	Date Started	Last Taken

5. Have you taken any caffeinated food or beverages in the last 8 hours? ..... Yes☐ 1 No ☐

6. Protocol:
   a. Consent form ..... Yes☐ 1 No ☐
   b. Stern message ..... Yes☐ 1 No ☐
   c. Questionnaire ..... Yes☐ 1 No ☐
   d. Spirometry ..... Yes☐ 1 No ☐
      1. BP _____
      2. Weight _____
      3. Height _____
      4. 5-min bronchodilator ..... Yes☐ 1 No ☐
   e. Dyspnea index ..... Yes☐ 1 No ☐
      post BD ..... Yes☐ 1 No ☐
   f. Blood draw (#_____) ..... Yes☐ 1 No ☐
      two 2ml aliquots
   g. Skin tests ..... Yes☐ 1 No ☐
   h. MDI (use next page) ..... Yes☐ 1 No ☐
   i. Peak flow meter ..... Yes☐ 1 No ☐

_____ initi

___/___/___ da
mo. day year

A. Item Analysis of Inhaler Use Checklist

1. Patient shakes inhaler for 5 seconds ..... Yes☐ 1 No ☐
2. Patient places the mouthpiece of the inhaler into one end of the spacer .... Yes☐ 1 No ☐
3. Patient positions the inhaler with the index finger on top of the medication cannister and thumb supporting the bottom of the inhaler ..... Yes☐ 1 No ☐
4. Patient places the spacer tube or mouthpiece between the teeth into the mouth ..... Yes☐ 1 No ☐
5. Patient closes mouth around spacer or mouthpiece ..... Yes☐ 1 No ☐
6. Patient exhales normally ..... Yes☐ 1 No ☐
7. Patient presses down the top of the medicaiton cannister with the index finger to release the medication ..... Yes☐ 1 No ☐
8. Patient inhales deeply and slowly while medication is being released ..... Yes☐ 1 No ☐
9. Patient holds the medication within the lungs a minimum of 10 seconds before exhaling ..... Yes☐ 1 No ☐
10. Patient waits a minimum of 2-3 minutes before repeating steps 1-9 for a second puff ..... Yes☐ 1 No ☐

B. BP ..... _____

Height ..... _____

Weight ..... _____

C. Dyspnea index ..... _____☐☐[

Post BD ..... _____☐☐[

D. Blood draw sample # ..... _____☐☐[

E. Peak Flow ..... _____☐☐[
L/min

_____ initials ____

F. Able to hold medication for required time: 01 NE 03 DY 02 mlo 04 mH

1. Caffeinated beverages ..... Yes☐ 1 No ☐
2. Anithistamines ..... Yes☐ 1 No ☐
3. Tablets ..... Yes☐ 1 No ☐
4. Inhalers ..... Yes☐ 1 No ☐
5. Other _____ Yes☐ 1 No ☐

Code as antihistamine "NO": elavil, doxepin, nortryptiline, amitryptiline Prozac, trazodone

Asthma History

Date of birth: ___/___/___

1. Has a doctor ever told you that your child has asthma? ..... Yes ☐ 1 No ☐

If yes . . .

a. Does he/she still have it? (Yes, if symptoms or medication use in past year) ..... Yes ☐ 1 No ☐

b. How old was your child at his/her first attack of asthma? _____

c. How old was your child during his/her most recent attack of asthma? _____

d. Does your child have chronic or seasonal asthma? ..... Seasonal ☐ 1 Chronic ☐

If seasonal . . .

Which months of the year does he/she usually have attacks of asthma? (CHECK ALL THAT APPLY)

	Yes	No
January/February	☐ 1	☐
March/April	☐ 1	☐
May/June	☐ 1	☐
July/August	☐ 1	☐
September/October	☐ 1	☐
November/December	☐ 1	☐

e. Has your child had an attack of asthma **in the last 12 months**? ..... Yes ☐ 1 No ☐

f. What was the trigger of the most recent attack? ..... infection ☐
exposure to allergen ☐
exposure to smoke, solvent, gas, dust, or fume ☐
other ☐
don't know ☐
cold air and exercise ☐

g. How sudden was the onset? ..... less than 12 hours ☐
12-24 hours ☐
(gradual) more than 24 hours ☐
don't know ☐

2. Has your child had an **attack** of asthma during or following exercise at any time **in the last 12 months**? ..... Yes ☐ 1 No ☐

3. Does your child usually cough, wheeze, or feel short of breath during the day? ..... Yes ☐ 1 No ☐
. . . or at night? ..... Yes ☐ 1 No ☐
(Usually means more than half the time)

If your child usually *coughs . . .*

a. Does your child cough on **most** days for as much as 3 months each year? ..... Yes ☐ 1 No ☐

b. Has he/she done this for at least 2 years? ..... Yes ☐ 1 No ☐

4. Does your child usually bring up any phlegm from his/her chest when coughing? ..... Yes ☐ 1 No ☐

5. During the last 4 weeks has your child been wheezing? ..... once or less per week ☐
2 times or more per week ☐
every day ☐

6. Has your child had nighttime asthma symptoms? ..... once or less per week ☐
(Awoke with wheezing, shortness of breath, or cough) 2 times or more per week ☐
every day ☐

Occupation

7. Has your child held a job (including baby-sitting)? ..... Yes ☐ 1 No ☐

If yes . . .

a. What was this job? [Be as precise as possible] _____

8. Does being at that job ever make your child's chest tight or wheezy? ..... Yes ☐ 1 No ☐

9. Has your child ever had to change or leave that job because it affected his/her breathing? ..... Yes ☐ 1 No ☐

10. Is your child's school or work attendance affected by asthma? ..... not at all ☐
(preschool, day care) usually ☐
always ☐

11. What triggered your child's first episode of asthma? ..... infection ☐
exposure to allergens ☐
exposure to smoke, gas, dust, solvent, or fume ☐
other ☐
don't know ☐
cold air and exercise ☐

Allergy History

12. Does your child have any nasal allergies including 'hay fever'? ..... Yes ☐
No ☐
Don't Know ☐

13. Has your child ever had eczema . . . ? ..... Yes ☐
No ☐
Don't Know ☐

a. . . . or any kind of skin allergy? ..... Yes ☐
No ☐
Don't Know ☐

14. Has your child ever had any difficulty with breathing or developed a cough after taking the following medications?

aspirin or aspirin-containing drug	Yes ☐ 1	No ☐
sulfa drugs	Yes ☐ 1	No ☐
penicillins	Yes ☐ 1	No ☐
other	Yes ☐ 1	No ☐

15. Has your child ever had any difficulty with breathing after eating dried fruit? ..... Yes ☐ 1 No ☐

16. Has your child ever had a reaction caused by eating a particular food or foods? ..... Yes ☐ 1 No ☐

If yes . . .

a. Has your child ever been hospitalized or treated in an emergency room because of a reaction to food? ..... Yes ☐ 1 No ☐

b. Has your child ever been diagnosed with food allergies? ..... Yes ☐ 1 No ☐

If yes . . .

1. By RAST test? ..... Yes ☐ 1 No ☐
2. By prick test? ..... Yes ☐ 1 No ☐
3. By intradermal skin testing? ..... Yes ☐ 1 No ☐
4. By double blind, placebo-controlled food challenge? ..... Yes ☐ 1 No ☐

c. Has your child nearly always had the same reaction after eating this type of food? ..... Yes ☐ 1 No ☐

d. What foods cause your child's symptoms? _____ ☐☐☐

31 crab	79 shrimp
33 egg	80 soy
53 milk	93 wheat
63 peanuts	

_____ ☐☐☐

_____ ☐☐☐

_____ ☐☐☐

_____ ☐☐☐

e. Do the reactions include: .....

	Yes	No
(pass out) loss of consciousness	☐ 1	☐
hives	☐ 1	☐
rash	☐ 1	☐
itchy skin	☐ 1	☐
diarrhea	☐ 1	☐
vomiting	☐ 1	☐
constipation	☐ 1	☐
stomach ache	☐ 1	☐
runny or stuffy nose	☐ 1	☐
headaches	☐ 1	☐
shortness of breath	☐ 1	☐
wheezing	☐ 1	☐
nausea	☐ 1	☐
colic	☐ 1	☐
sore throat	☐ 1	☐
dizziness	☐ 1	☐
swollen tongue	☐ 1	☐
throat closing off	☐ 1	☐

17. Did your child have colic as an infant? ..... Yes ☐ 1 No

If yes . . .

a. Was the colic ever associated with a particular food? ..... Yes ☐ 1 No

If yes . . .

1. Which food? _____ ☐☐

_____ ☐☐

18. I am going to read a list of allergic-type responses, such as hay fever, asthma, etc. Please me which of your child's blood relatives, if any, have been affected by these.

	Sisters	Brothers	Mother	Father	Aunts	Uncles	Grandpar
Hay fever, nasal allergies							
Asthma							
Eczema							
Hives							
Adverse reaction to food							
None/Don't know							

19. Has your child received allergy shots at any time? ..... Yes ☐ 1 No ☐

If yes . . .

a. Has he/she had allergy shots in the last 12 months? ..... Yes ☐ 1 No ☐

More about your child

20. Did your child go to a school, playschool or nursery with other children before the age of 5 years? ..... Yes ☐
No ☐
Don't Know ☐

21. Did your child have a serious respiratory infection before the age of 5 years? ..... Yes ☐
No ☐
Don't Know ☐

Animals, dust and feathers

22. Is there a cat in the child's home? ..... Yes ☐ 1 No ☐

If yes . . .

a. Does the cat stay outside the house all the time? ..... Yes ☐ 1 No ☐

b. Is the cat **ever** allowed into the child's bedroom? ..... Yes ☐ 1 No ☐

23. Is there a dog in the child's home? ..... Yes ☐ 1 No ☐

If yes . . .

a. Does the dog stay outside the house all the time? ..... Yes ☐ 1 No ☐

b. Is the dog **ever** allowed into your child's bedroom? ..... Yes ☐ 1 No ☐

24. Are there any birds in the child's home? ..... Yes ☐ 1 No ☐

If yes . . .

a. Are any of these birds kept inside the house? ..... Yes ☐ 1 No ☐

25. When your child is near animals, feathers, or dust, does he/she ever .....

	Yes	No
start to cough?	☐ 1	☐
start to wheeze?	☐ 1	☐
get a feeling of tightness in your chest?	☐ 1	☐
start to feel short of breath?	☐ 1	☐
get a runny or a stuffy nose or start to sneeze?	☐ 1	☐
get itchy or watering eyes?	☐ 1	☐

Trees, grass, plants, flowers and pollen

26. When your child is near trees, grass or flowers, or when there is a lot of pollen about, does he/she ever .....

	Yes	No
start to cough?	☐ 1	☐
start to wheeze?	☐ 1	☐
get a feeling of tightness in his/her chest?	☐ 1	☐
start to feel short of breath?	☐ 1	☐
get a runny or a stuffy nose or start to sneeze?	☐ 1	☐
get itchy or watering eyes?	☐ 1	☐

If yes to any of the above. . .

a. Which time of year does this happen? .....

	Yes	No
winter	☐ 1	☐
spring	☐ 1	☐
summer	☐ 1	☐
autumn	☐ 1	☐

Your child's home

27. Which best describes the building in which your child lives?

a single family house detached from any other house	☐
a building for two families	☐
a building for three or four families	☐
a building for five or more families	☐
mobile home	☐
other	☐
don't know	☐

28. Does the home have an air-filtering device .....

	Yes	N
central (on furnace)?	☐ 1	☐
free-standing in room?	☐ 1	☐

29. Does your child's home have any of the following?
(CHECK ALL THAT APPLY)

- central heating ☐
- forced air heating ☐
- air conditioning (central or individual units) ☐
- radiators ☐
- electric heaters ☐

30. Which of the following is used in the child's home for heating and for hot water?
(CHECK ALL THAT APPLY)

- fireplace/woodstove ☐
- electric heater ☐
- gas-fired boiler or gas furnace ☐
- oil-fired boiler or oil furnace ☐
- heat pump ☐
- other ☐

31. Which of the following is used in the child's home for cooking? .....gas ☐
(CHECK ALL THAT APPLY)

- electric ☐
- microwave ☐
- other ☐

32. Does the room your child uses most at home during the day.....

	Yes	No
have wall to wall carpeting?	☐ 1	☐
contain area rugs?	☐ 1	☐
have double paned windows? (e.g. storm or thermal windows)	☐ 1	☐
have curtains/drapes?	☐ 1	☐
have upholstered furnishings? (e.g. fabric)	☐ 1	☐

33. Does your child's bedroom .....

	Yes	No
have wall to wall carpeting?	☐ 1	☐
contain area rugs?	☐ 1	☐
have double paned windows? (e.g. storm or thermal windows)	☐ 1	☐
have curtains/drapes?	☐ 1	☐
have a conventional mattress?	☐ 1	☐
have a feather pillow?	☐ 1	☐
have a down comforter?	☐ 1	☐
have a feather bed/mattress?	☐ 1	☐

34. Has there ever been mold or mildew on any surface, other than food, inside the child's home? ..... Yes ☐ 1 No ☐

If yes . . .

a. Which rooms have been affected?
(CHECK ALL THAT APPLY)

bathrooms(s) ☐
bedroom(s) ☐
living area(s) ☐
kitchen ☐
basement or attic ☐
other ☐

b. Has there been mold or mildew on any surfaces inside the child's home **in the last 12 months**? ..... Yes ☐ 1 No ☐

35. Do you use a humidifier, including any humidifier system built into the heating system of the child's home? ..... Yes ☐ 1 No ☐

If yes . . .

a. What type of humidifier?
(CHECK ALL THAT APPLY)

humidifier built into heating system ☐
portable cold mist - ultrasonic or spinning disc ☐
portable hot mist vaporizer ☐
other ☐

b. Under what circumstances is the humidifier used?

only when someone is ill—in the room ☐
to humidify the house ☐
other ☐

Smoking

36. Has your child ever smoked for as long as a year? ..... Yes ☐ 1 No ☐
['YES' means at least 20 packs of cigarettes in a lifetime, or at least one cigarette per day or one cigar a week for one year]

If yes . . .

a. At what age did your child start smoking? _____

b. Is your child a current smoker, as of one month ago? ..... Yes ☐ 1 No ☐

If your child is a current smoker . . .

c. How much on average? ..... number of cigarettes/day _
number of cigars/week _
pipe tobacco in ounces/week _
or grams/week _
number of joints of marijuana/week _

d. Does your child smoke substances besides tobacco? ..... Yes ☐ 1 No ☐

If your child has stopped or cut down . . .

e. How old was your child when he/she stopped or cut down smoking? _____

f. On average of the entire time he/she smoked, before stopping or cutting down, how much did he/she smoke? ..... number of cigarettes/day _
number of cigars/week _
pipe tobacco in A) ounces/week _
or B) grams/week _
number of joints of marijuana/week _

g. Did your child smoke substances besides tobacco? ..... Yes ☐ 1 No ☐

37. Has your child been **regularly** exposed to **other people's** tobacco smoke in the last 12 months?
['Regularly' means on most days or nights] ..... Yes ☐ 1 No ☐

If yes . . .

a. How many hours per day is the child exposed to other people's tobacco smoke? _____ (leading zero)

b. How many people smoke regularly? _____ (leading zero)

c. Do people smoke regularly in the room where your child is? ..... Yes ☐ 1 No ☐

Medications

38. Is your child currently taking any medication, including inhalers, aerosols, and tablets for asthma? ..... Yes ☐ 1 No ☐

39. Has your child used any inhalers (through the mouth) to help breathing at any time **in the last 12 months**? ..... Yes ☐ 1 No ☐

If yes . . .

Which of the following have been used (include over-the-counter)?
(SEE ALPHABETIZED CARD)

- beta-2-agonist inhalers ☐
- non-specific beta agonist inhalers ☐
- anti-muscarinic inhalers (anticholinergic) ☐
- inhaled steroids ☐
- cromolyn sodium ☐
- other inhalers [non-steroid, single drug] ☐
- inhaled compound bronchodilators ☐

40. How often does your child use a beta agonist inhaler? ..... less than 2 puffs daily ☐
    2-4 puffs daily ☐
    4-8 puffs daily ☐
    more than 8 puffs daily ☐
    NA ☐

    *if uses prn, when using inhaler how often is it used?

41. Has your child used any **nebulized** medication **in the last 12 months**? ..... Yes☐ 1 No ☐

If yes . . .

Which of the following have been used?
(SEE ALPHABETIZED CARD)

- beta-2-agonists ☐
- non-specific beta agonists ☐
- anti-muscarinic inhalers (anticholinergic) ☐
- steroids ☐
- cromolyn sodium ☐
- other inhalers [non-steroid, single drug] ☐
- compound bronchodilators ☐
- unknown ☐

42. Has your child used any pills, tablets, syrups or other medications to help breathing at any time **in the last 12 months**? ..... Yes☐ 1 No ☐

If yes . . .

Which ones were used (inlcude over-the-counter)?

- specific beta-2-agonists ☐
- non-specific agonists ☐
- steroids ☐
- methylxanthines ☐
- decongestants/antihistamines ☐

43. Has your child used any nasal inhalers in the last 12 months? ..... Yes☐ 1 No ☐

If yes . . .

Which ones were used (inlcude over-the-counter)?

- antihistamines ☐
- decongestants ☐
- steroids ☐
- cromolyn ☐
- _____ other ☐

44. Does your child take medications every day to help breathing even without shortness of breath? ..... Yes ☐ 1 No ☐

If yes . . .

a. Which medications? _____ ☐☐☐

b. _____ ☐☐☐

45. Does your child take any medications only for attacks of breathlessness? .. Yes ☐ 1 No ☐

If yes . . .

a. Which medications? _____ ☐☐☐

b. _____ ☐☐☐

c. Does your child take these medications ..... at the onset of the attack? ☐

only when the attack becomes more severe? ☐

46. Does your child use steroid tablets during an acute asthma attack? ..... not at all ☐

sometimes (less than 50% of the time) ☐

usually (more than 50% of the time) ☐

47. Has your child had any injections to help breathing at any time in the last 12 months? ..... Yes ☐ 1 No ☐

If yes . . .

a. Which medications? ..... epinephrine ☐

~~immunotherapy~~ ☐

other ☐

48. Has your child used any other remedies to help breathing at any time in the last 12 months? ..... Yes ☐ 1 No ☐

If yes . . .

a. Which remedies? _____ ☐☐

b. _____ ☐☐

49. Has your child used a peak flow meter in the last year? ..... Yes ☐ 1 No ☐

50. When your child has been prescribed medicines for breathing . . .

a. Does he/she normally take (CHECK ONE BOX) .... all of the medication as prescribed? ☐

most of the medication? ☐

some of the medication? ☐

none of the medication? ☐

b. When breathing gets worse, and he/she is prescribed medication for breathing, does he/she normally take ..... all of the medication as prescribed? ☐

most of the medication? ☐

some of the medication? ☐

none of the medication? ☐

51. Do you think it is bad for your child to take medication all the time to help breathing? ..... Yes ☐ 1 No ☐

52. Do you think your child should take as much medicine as needed to get rid of *all* breathing problems? ..... Yes ☐ 1 No ☐

53. How confident are you that when your child uses medications they will work?
very confident ☐
confident ☐
not very confident ☐

Physicians

54. Is your child's primary care provider ..... an asthma specialist (allergist or pulmonologist)? ☐
a non-asthma specialist? ☐
not a physician? ☐

coding ↓
KP NOT ON LIST 99980
NOT KP DR 99990
DONT KNOW 99999

a. What is that person's name? _____ ☐☐☐☐☐
(multiple names - draw line through boxes)

b. When was your child last seen? ___/___/___
mo. day year

which clinic? _____ (do not code)

55. Has your child ever been seen by an asthma specialist? ..... yes, once ☐
yes, more than once ☐
no ☐

If yes . . .

a. What was that person's name? _____ ☐☐☐☐☐

b. When was your child last seen? ___/___/___
mo. day year

c. Name of clinic: _____ ☐☐

56. Has your child ever been seen by a naturopath, chiropractor or acupuncturist for asthma? ..... Yes ☐ 1 No ☐

57. When was the last time your child was seen by a doctor because of breathing problems or because of shortness of breath? ..... within last 7 days ☐
more than 7 days ago but within last 4 weeks ☐
more than 4 weeks ago but within last 12 months ☐
more than a year ago ☐

Coding 210: 01 Dr listed Q54 (or 54+55)
02 " " Q55
03 KP NOT LISTED 54 or 55
04 KP DONT KNOW
05 NOT KP
06 DONT KNOW

a. Who was your child seen by? ..... non-specialist ☐
specialist ☐
don't know ☐

b. What was the person's name? _____ ☐

c. Where was your child seen? ..... office ☐
walk-in (UCC) or emergency room ☐
hospital ☐

58. Has your child ever spent a night in a hospital because of breathing problems? ..... Yes ☐ 1 No ☐

If yes . . .
a. How many times in the last 12 months? _____

59. Has your child ever visited an urgency care clinic because of breathing problems? ... Yes ☐ 1 No ☐

60. Has your child ever visited an emergency room because of breathing problems? ..... Yes ☐ 1 No ☐

If yes . . .
a. Was medication taken first?
(CHECK ALL THAT APPLY)

DONT KNOW - draw line through boxes

aminophylline ☐
beta agonist ☐
corticosteroid ☐
epinephrine ☐
atrovent ☐
no medication ☐
other ☐

61. Do you think if your child used medications appropriately there would be a lower chance of going to the ER or the hospital? ..... Yes ☐ 1 No ☐

Managing an asthma attack

62. Now I would like to ask some questions about what you do when your child does have a asthma attack. During the early stages of an asthma attack, or when your child is having mild asthma symptoms, what do you usually do for it?

a. give medicines ..... Yes ☐ 1 No ☐
b. call a physician ..... Yes ☐ 1 No ☐
c. check air flow ..... Yes ☐ 1 No ☐
d. go to the hospital ..... Yes ☐ 1 No ☐

Response to wheeze

63. Do you remember the last time your child wheezed or coughed from asthma? ..... Yes ☐ 1 No ☐

If yes . . .

a. When was that? _____

I'd like you to think about what your child did that last time to take care of his/her asthm

	Yes	No	Not mention
b. Told parent or another adult	☐ 1	☐ 2	☐
c. Took asthma medicine	☐ 1	☐ 2	☐
d. Went to doctor or hospital	☐ 1	☐ 2	☐

Child health status measures

64. In general, would you say that this child's health is excellent, good, fair, or poor? ..... excellent ☐
good ☐
fair ☐
poor ☐

65. During the last 3 months, how much have you worried about this child's health? ..... a great deal ☐
somewhat ☐
a little ☐
not at all ☐

66. During the last 3 months, how much pain or distress has this child's health caused her/him? ..... a great deal ☐
some ☐
a little ☐
not at all ☐

67 . Please check one of the boxes to indicate whether the following statements are true or fals **for this child. There are no right or wrong answers.** Some of the statements may loo or seem like others, but each statement is different and should be rated by itself.

a. Your child's health is excellent ..... definitely true ☐
mostly true ☐
don't know ☐
mostly false ☐
definitely false ☐

b. Your child seems to resist illness very well ..... definitely true ☐
mostly true ☐
don't know ☐
mostly false ☐
definitely false ☐

c. Your child seems to be less healthy than other children you know ..... definitely true ☐
mostly true ☐
don't know ☐
mostly false ☐
definitely false ☐

d. When there is something going around, your child usually catches it .... definitely true ☐
mostly true ☐
don't know ☐
mostly false ☐
definitely false ☐

How well has your child been?

Here are some statements that parents have made to describe their children. Please answer them thinking about your child during the last two weeks.

During the last two weeks, how often did your child: FOR STAFF USE ON

68. Eat well ..... Never or rarely ☐ 1* Yes ☐
Some of the time ☐ 2* Sometimes ☐
Almost always ☐ 3 No ☐

69. Sleep well ..... Never or rarely ☐ 1* Yes ☐
Some of the time ☐ 2* Sometimes ☐
Almost always ☐ 3 No ☐

70. Seem contented and cheerful ..... Never or rarely ☐ 1* Yes ☐
Some of the time ☐ 2* Sometimes ☐
Almost always ☐ 3 No ☐

71. Act moody ..... Never or rarely ☐ 1 Yes ☐
Some of the time ☐ 2* Sometimes ☐
Almost always ☐ 3* No ☐

72. Communicate what he/she wanted ..... Never or rarely ☐ 1* Yes ☐
Some of the time ☐ 2* Sometimes ☐
Almost always ☐ 3 No ☐

73. Seem to feel sick and tired ..... Never or rarely ☐ 1 Yes ☐
Some of the time ☐ 2* Sometimes ☐
Almost always ☐ 3* No ☐

74. Occupy him/herself ..... Never or rarely ☐ 1* Yes ☐
Some of the time ☐ 2* Sometimes ☐
Almost always ☐ 3 No ☐

75. Seem lively and energetic ..... Never or rarely ☐ 1* Yes ☐
Some of the time ☐ 2* Sometimes ☐
Almost always ☐ 3 No ☐

76. Seem unusually irritable ..... Never or rarely ☐ 1 — Yes ☐
Some of the time ☐ 2* — Sometimes ☐
Almost always ☐ 3* — No ☐

77. Sleep through the night ..... Never or rarely ☐ 1* — Yes ☐
Some of the time ☐ 2* — Sometimes ☐
Almost always ☐ 3 — No ☐

78. Respond to your attention ..... Never or rarely ☐ 1* — Yes ☐
Some of the time ☐ 2* — Sometimes ☐
Almost always ☐ 3 — No ☐

79. Seem unusually difficult ..... Never or rarely ☐ 1 — Yes ☐
Some of the time ☐ 2* — Sometimes ☐
Almost always ☐ 3* — No ☐

80. Seem interested in what was going on around him/her ..... Never or rarely ☐ 1* — Yes ☐
Some of the time ☐ 2* — Sometimes ☐
Almost always ☐ 3 — No ☐

81. React to things by crying ..... Never or rarely ☐ 1 — Yes ☐
Some of the time ☐ 2* — Sometimes ☐
Almost always ☐ 3* — No ☐

Demographics

82. Education: Years of regular school completed.
(CHECK HIGHEST LEVEL COMPLETED ONLY)

grades 0-8 ☐
grades 9-11 ☐
high school ☐
some college ☐
college graduate ☐
post-college work ☐

83. Which of the following socioeconomic groups would you say best describes you? ..... upper class ☐
upper middle ☐
middle ☐
working ☐
lower ☐

84. Here is a list of different yearly income groups. Which group comes closest to the total amount that all members of the household combined received last year from all sources before taxes? .....

less than $4,999 ☐ 1	$30,000-$34,999 ☐
$5,000-$9,999 ☐ 2	$35,000-$39,999 ☐
$10,000-$14,999 ☐ 3	$40,000-$49,999 ☐
$15,000-$19,999 ☐ 4	$50,000-$59,999 ☐
$20,000-$24,999 ☐ 5	$60,000-$69,999 ☐
$25,000-$29,999 ☐ 6	$70,000 and more ☐

85. Would you characterize your child's race as .....

Caucasian ☐
Hispanic ☐
American Indian ☐
Asian ☐
African ☐
African-American ☐
other: ☐

Thank You!

Today's date: ___/___/___
mo. day ye

Allergy Testing Protocol

1	9
2	10
3	11
4	12
5	13
6	14
7	15
8	

1 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

2 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

positive control

3 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

4 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

5 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

6 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

7 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

8 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

9 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

10 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

11 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

12 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

negative control

13 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

14 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

15 1st diam 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

2/24/93 ADULT

1. How do you feel without your medications? ..... quite symptomatic ☐
   (If symptomatic, perform spirometry & give medications) okay ☐

2. Check that address and telephone number are correct (additional telephone for follow-up if necessary) _____

3. Social security number:

4. What medications are you currently taking (include over-the-counter)

Name (generic)	Dose	Frequency	Date Started	Last Taken

5. Have you taken any caffeinated food or beverages in the last 8 hours? ..... Yes☐ 1 No ☐

6. Protocol:
   a. Consent form ..... Yes☐ 1 No ☐
   b. Stern message ..... Yes☐ 1 No ☐
   c. Questionnaire ..... Yes☐ 1 No ☐
   d. Spirometry ..... Yes☐ 1 No ☐
      1. BP _____
      2. Weight _____
      3. Height _____
      4. 5-min bronchodilator ..... Yes☐ 1 No ☐
   e. Dyspnea index ..... Yes☐ 1 No ☐
      post BD ..... Yes☐ 1 No ☐
   f. Blood draw (#_____) ..... Yes☐ 1 No ☐
      two 2ml aliquots
   g. Skin tests ..... Yes☐ 1 No ☐
   h. MDI (use next page) ..... Yes☐ 1 No ☐
   i. Peak flow meter ..... Yes☐ 1 No ☐

_____ init

___/___/___ c
mo. day year

DS 4288 2/24/93 Study ID#_____

A. Item Analysis of Inhaler Use Checklist

1. Patient shakes inhaler for 5 seconds ..... Yes☐ 1 No
2. Patient places the mouthpiece of the inhaler into one end of the spacer.... Yes☐ 1 No
3. Patient positions the inhaler with the index finger on top of the medication cannister and thumb supporting the bottom of the inhaler ..... Yes☐ 1 No
4. Patient places the spacer tube or mouthpiece between the teeth into the mouth ..... Yes☐ 1 No
5. Patient closes mouth around spacer or mouthpiece ..... Yes☐ 1 No
6. Patient exhales normally ..... Yes☐ 1 No
7. Patient presses down the top of the medicaiton cannister with the index finger to release the medication ..... Yes☐ 1 No
8. Patient inhales deeply and slowly while medication is being released ..... Yes☐ 1 No
9. Patient holds the medication within the lungs a minimum of 10 seconds before exhaling ..... Yes☐ 1 No
10. Patient waits a minimum of 2-3 minutes before repeating steps 1-9 for a second puff ..... Yes☐ 1 No

B. BP ..... _____

Height ..... _____

Weight ..... _____

C. Dyspnea index ..... _____☐☐

Post BD ..... _____☐☐

D. Blood draw sample # ..... _____☐☐☐

E. Peak Flow ..... _____☐☐☐

L/min

_____ initials ___

01 HE 03 DY
02 MO 04 MH

F. Able to hold medication for required time:

1. Caffeinated beverages ..... Yes☐ 1 No ☐
2. Anithistamines ..... Yes☐ 1 No ☐
3. Tablets ..... Yes☐ 1 No ☐
4. Inhalers ..... Yes☐ 1 No ☐
5. Other _____ Yes☐ 1 No ☐

Code as antihistamine "No": elavil, doxepin, nortryptiline, amitryptiline
PROZAC, trazodone

DS 4281 2/24/93 **Adult** Study ID#_____

Asthma History

Date of birth: ___/___/___

1. Has a doctor ever told you that you have asthma? ..... Yes☐ 1 No

If yes . . .

a. Do you still have it? (Yes, if symptoms or medication use in past year) .... Yes☐ 1 No

b. How old were you when you had your first attack of asthma? _____

c. How old were you when you had your most recent attack of asthma? _____

d. Do you have chronic or seasonal asthma? ..... Seasonal☐ 1 Chronic

If seasonal . . .

Which months of the year do you usually have attacks of asthma? ..... Yes
(CHECK ALL THAT APPLY)

January/February	☐ 1
March/April	☐ 1
May/June	☐ 1
July/August	☐ 1
September/October	☐ 1
November/December	☐ 1

e. Have you had an attack of asthma **in the last 12 months**? ..... Yes☐ 1 No

f. What triggered the most recent attack? ..... infection
exposure to allergen
exposure to smoke, solvent, gas, dust, or fume
other
don't know
cold air and exercise

g. How sudden was the onset? ..... less than 12 hours
12-24 hours
(gradual) more than 24 hours
don't know

h. What triggered your first episode of asthma? _____

2. Have you had an **attack** of asthma during or following exercise at any time **in the last 12 months**? ..... Yes☐ 1 No

3. Do you usually cough, wheeze, or feel short of breath during the day? ..... Yes ☐ 1 No
. . . or at night? ..... Yes ☐ 1 No
(Usually means more than half the time)

If you usually cough . . .

a. Do you cough on **most** days for as much as 3 months each year? ..... Yes☐ 1 No

b. Have you done this for at least two years? ..... Yes☐ 1 No

4. Do you usually bring up any phlegm from your chest when you cough? ..... Yes☐ 1 No

5. During the last 4 weeks have you been wheezing? ..... once or less per week ☐
2 times or more per week ☐
every day ☐

6. Have you had nighttime asthma symptoms? ..... once or less per week ☐
(Awoke with wheezing, shortness of breath, or cough) 2 times or more per week ☐
every day ☐

Occupation

7. Are you currently employed? ..... Yes☐ 1 No ☐
disabled, never employed ☐

If No . . .

a. Are you looking for a job? ..... Yes☐ 1 No ☐

8. What is or was your current or most recent job? _____ ☐☐

a. What is the business, field, or industry? _____ ☐☐

9. How often are you exposed to the following on the job?

	Not at all	Some of the time	Most the tir
a1. solvents	☐ 1	☐ 2	☐
a2. fumes	☐ 1	☐ 2	☐
a3. dusts	☐ 1	☐ 2	☐
a4. cigarette smoke of others	☐ 1	☐ 2	☐
a5. gases	☐ 1	☐ 2	☐
a6. other _____			

b. How long have you had this exposure (in years)? _____ ☐☐

c. What agent were you exposed to? _____ ☐

10. Does being at work ever make your chest tight or wheezy? ..... Yes☐ 1 No ☐

11. Have you ever had to change or leave your job because it affected your breathing? ..... Yes☐ 1 No ☐

If yes . . .

a. What was this job? [Be as precise as possible] _____ ☐☐

b. What agent were you exposed to? _____ ☐

12. Is your school or work attendance affected by asthma? ..... not at all ☐
a little ☐
usually ☐
always ☐

Allergy History

13. Do you have any nasal allergies including 'hay fever'? ..... Yes [
No [
Don't Know [

14. Have you ever had eczema? ..... Yes [
No [
Don't Know [

15. Have you ever had any kind of skin allergy? ..... Yes [
No [
Don't Know [

16. Have you ever had any difficulty with your breathing or developed a cough after taking the following medications?

aspirin or aspirin-containing drug ..... Yes☐ 1 No ☐
sulfa drugs ..... Yes☐ 1 No ☐
penicillins ..... Yes☐ 1 No ☐
other ..... Yes☐ 1 No ☐

17. Do you have symptoms of heartburn? ..... Yes☐ 1 No ☐
. . . have hiatal hernia? ..... Yes☐ 1 No ☐
. . . have acid taste in your mouth? ..... Yes☐ 1 No ☐
. . . require frequent antacids? ..... Yes☐ 1 No ☐
. . . take H2 blockers (Tagamet, Zantac, cimetidine, ranitidine, omeprazole)? .. Yes☐ 1 No ☐

18. Have you ever had any difficulty with your breathing after eating dried fruit or drinking wine or beer? ..... Yes☐ 1 No ☐

19. Have you ever had a reaction caused by eating a particular food or foods? ..... Yes☐ 1 No ☐

If yes . . .

a. Have you nearly always had the same reaction after eating this type of food? ..... Yes☐ 1 No ☐

b. Have you ever been hospitalized or treated in an emergency room because of a reaction to food? ..... Yes ☐ 1 No ☐

c. Have you ever been diagnosed with food allergies? ..... Yes ☐ 1 No ☐

If yes . . .

1. by RAST test? ..... Yes ☐ 1 No ☐
2. by prick test? ..... Yes ☐ 1 No ☐
3. by intradermal skin testing? ..... Yes ☐ 1 No ☐
4. by double blind, palcebo-controlled food challenge? ..... Yes ☐ 1 No ☐

b. What foods cause your symptoms?

31 crab	79 shrimp
33 egg	80 soy
53 milk	93 wheat
63 peanuts	

_____ ☐☐☐
_____ ☐☐☐
_____ ☐☐☐
_____ ☐☐☐
_____ ☐☐☐

c. Do the reactions include: .....

	Yes	No
hives	☐ 1	☐
rash	☐ 1	☐
itchy skin	☐ 1	☐
diarrhea	☐ 1	☐
vomiting	☐ 1	☐
constipation	☐ 1	☐
stomach pains	☐ 1	☐
runny or stuffy nose	☐ 1	☐
headaches	☐ 1	☐
shortness of breath	☐ 1	☐
wheezing	☐ 1	☐
nausea	☐ 1	☐
tongue swelling / throat closing off	☐ 1	☐
sore throat	☐ 1	☐
dizziness	☐ 1	☐
loss of consciousness (pass out)	☐ 1	☐

20. How many cups of caffeinated beverages do you drink a day? ..... None ☐
1 ☐
2 ☐
3+ ☐

21. I am going to read a list of allergic-type responses, such as hay fever, asthma, etc. Please te me which of your blood relatives, if any, have been affected by these.

	Sisters	Brothers	Mother	Father	Children	Aunts	Uncles	Grandparen
Hay fever, nasal allergies								
Asthma								
Eczema								
Hives								
Adverse reaction to food								
None/Don't Know								

22. Have you received allergy shots at any time in your life? ..... Yes ☐ 1 No ☐

If yes . . .

a. Have you had allergy shots in the last 12 months? ..... Yes ☐ 1 No ☐

More about yourself

23. Did you go to a school, playschool or nursery with other children before the age of 5 years? ..... Yes ☐
No ☐
Don't Know ☐

24. Did you have a serious respiratory infection before the age of 5 years? ..... Yes ☐
No ☐
Don't Know ☐

Animals, dust and feathers

25. Do you own a cat? ..... Yes ☐ 1 No ☐

If yes . . .

a. Does your cat stay outside the house all the time? ..... Yes ☐ 1 No ☐

b. Is your cat **ever** allowed into your bedroom? ..... Yes ☐ 1 No ☐

26. Do you own a dog? ..... Yes ☐ 1 No ☐

If yes . . .

a. Does your dog stay outside the house all the time? ..... Yes ☐ 1 No ☐

b. Is your dog **ever** allowed into your bedroom? ..... Yes ☐ 1 No ☐

27. Do you own any birds? ..... Yes ☐ 1 No ☐

If yes . . .

a. Are any of these birds kept inside the house? ..... Yes ☐ 1 No ☐

28. When you are near animals, feathers, or dust (such as when vaccuuming), do you ever .....

	Yes	No
start to cough?	☐ 1	☐
start to wheeze?	☐ 1	☐
get a feeling of tightness in your chest?	☐ 1	☐
start to feel short of breath?	☐ 1	☐
get a runny or a stuffy nose or start to sneeze?	☐ 1	☐
get itchy or watering eyes?	☐ 1	☐

Trees, grass, plants, flowers and pollen

29. When you are near trees, grass or flowers, or when there is a lot of pollen about, do you ever .....

	Yes	No
start to cough?	☐ 1	☐
start to wheeze?	☐ 1	☐
get a feeling of tightness in your chest?	☐ 1	☐
start to feel short of breath?	☐ 1	☐
get a runny or a stuffy nose or start to sneeze?	☐ 1	☐
get itchy or watering eyes?	☐ 1	☐

If yes to any of the above. . .

a. Which time of year does this happen? .....

	Yes	
winter	☐ 1	☐
spring	☐ 1	☐
summer	☐ 1	☐
autumn	☐ 1	☐

Your home

30. Which best describes the building in which you live?

a single family house detached from any other house	☐
a building for two families	☐
a building for three or four families	☐
a building for five or more families	☐
mobile home	☐
other	☐
don't know	☐

31. Does your home have an air-filtering device? .....

	Yes	No
central (on furnace)	☐ 1	☐
free-standing in room	☐ 1	☐

32. Does your home have any of the following?
(CHECK ALL THAT APPLY)

central heating	☐
forced air heating	☐
air conditioning (central or individual units)	☐
radiators	☐
electric heaters	☐

33. Which of the following do you use for heating and for hot water?
(CHECK ALL THAT APPLY)

fireplace/woodstove	☐
electric heater	☐
gas-fired boiler or gas furnace	☐
oil-fired boiler or oil furnace	☐
heat pump	☐
other	☐

34. Which of the following do you use for cooking?
(CHECK ALL THAT APPLY)

gas	☐
electric	☐
microwave	☐
other	☐

35. Does the room which you use most at home during the day .....

	Yes	N
have wall to wall carpeting?	☐ 1	☐
contain area rugs?	☐ 1	☐
have double paned windows? (e.g. storm or thermal windows)	☐ 1	☐
have curtains/drapes?	☐ 1	☐
have upholstered furnishings? (e.g. fabric)	☐ 1	☐

36. Does your bedroom .....

	Yes	N
have wall to wall carpeting?	☐ 1	☐
contain area rugs?	☐ 1	☐
have double paned windows? (e.g. storm or thermal windows)	☐ 1	☐
have curtains/drapes?	☐ 1	☐
have a conventional mattress?	☐ 1	☐
have feather pillows?	☐ 1	☐
have a down comforter?	☐ 1	☐
have a feather bed/mattress?	☐ 1	☐

37. Has there ever been mold or mildew on any surface, other than food, inside the home? ..... Yes ☐ 1 No ☐

If yes . . .

a. Which rooms have been affected?
(CHECK ALL THAT APPLY)

- bathrooms(s) ☐
- bedroom(s) ☐
- living area(s) ☐
- kitchen ☐
- basement or attic ☐
- other ☐

Has there been mold or mildew on any surfaces inside the home in the last 12 months? ..... Yes ☐ 1 No ☐

38. Do you use a humidifier, including any humidifier system built into your heating system? ..... Yes ☐ 1 No ☐

If yes . . .

a. What type of humidifier do you use?
(CHECK ALL THAT APPLY)

- humidifier built into heating system? ☐
- portable cold mist - ultrasonic or spinning disc ☐
- portable hot mist vaporizer ☐
- other ☐

b. Under what circumstances do you use your humidifier?

- only when someone is ill—in the room ☐
- to humidify the house ☐
- other ☐

Smoking

39. Have you ever smoked for as long as a year? ..... Yes☐ 1 No ☐
['YES' means at least 20 packs of cigarettes in a lifetime, or at least one cigarette per day or one cigar a week for one year]

If yes . . .

a. How old were you when you started smoking? _____ ☐☐

b. Are you a current smoker, as of one month ago? ..... Yes☐ 1 No ☐

If you are a current smoker . . .

c. How much do you now smoke on average?
number of cigarettes/day ___
number of cigars/week ___
pipe tobacco in ounces/week ___
or grams/week ___
number of joints of marijuana/week ___

d. Do you smoke substances besides tobacco? ..... Yes☐ 1 No ☐

If you have stopped or cut down . . .

e. How old were you when you stopped or cut down smoking? _____ ☐☐

f. On average of the entire time you smoked, before you stopped or cut down, how much did you smoke?
number of cigarettes/day ___
number of cigars/week ___
pipe tobacco in A) ounces/week ___
or B) grams/week ___
number of joints of marijuana/week ___

d. Did you smoke substances besides tobacco? ..... Yes☐ 1 No ☐

40. Have you been **regularly** exposed to **other people's** tobacco smoke in the last 12 months?
['Regularly' means on most days or nights] ..... Yes☐ 1 No ☐ 2

If yes . . .

a. How many hours per day are you exposed to other people's tobacco smoke? _____ (leading zero)

b. Not counting yourself, how many people in your household smoke regularly? _____ (leading zero)

c. Do people smoke regularly in the room where you work? ..... Yes☐ 1 No ☐ 2

Medications

41. Are you currently taking any medication—including inhalers, aerosols, or tablets—for asthma? ..... Yes☐ 1 No ☐ 2

42. Have you used any **inhalers** (through the mouth) to help your breathing at any time **in the last 12 months**? ..... Yes☐ 1 No ☐

If yes . . .

a. Which of the following have been used (include over-the-counter)? (SEE ALPHABETIZED CARD)

beta-2-agonist inhalers ☐
non-specific beta agonist inhalers ☐
c. anti-muscarinic inhalers (anticholinergic) ☐
inhaled steroids ☐
cromolyn sodium ☐
other inhalers [non-steroid, single drug] ☐
inhaled compound bronchodilators ☐

b. How often do you use beta agonist inhalers? ..... less than 2 puffs daily ☐
2-4 puffs daily ☐
4-8 puffs daily ☐
more than 8 puffs daily ☐
NA ☐

* if uses prn, when using inhaler how often is it used?

43. Have you used any **nebulized** medication **in the last 12 months**? ..... Yes☐ 1 No ☐

If yes . . .

Which of the following have been used? (SEE ALPHABETIZED CARD)

beta-2-agonists ☐
non-specific beta agonists ☐
anti-muscarinic inhalers (anticholinergic) ☐
steroids ☐
cromolyn sodium ☐
other inhalers [non-steroid, single drug] ☐
compound bronchodilators ☐
unknown ☐

44. Have you used any pills, tablets, syrups or other medications to help your breathing at any time **in the last 12 months**? ..... Yes☐ 1 No ☐

If yes . . .

Which ones have you used (include over-the-counter)?

beta-2-agonist inhalers ☐
non-specific beta agonists ☐
steroids ☐
methylxanthines ☐
decongestants/antihistamines ☐

45. Have you used any nasal inhalers in the last 12 months? ..... Yes☐ 1 No ☐

If yes . . .

Which ones have you used (include over-the-counter)?

antihistamines ☐
decongestants ☐
steroids ☐
cromolyn ☐
_____ other ☐

46. Do you take medications every day to help your breathing even if you don't feel short of breath? ..... Yes☐ 1 No ☐

If yes . . .

a. Which medications? _____ ☐☐ ☐

b. _____ ☐☐ ☐

47. Do you take any medications only for attacks of breathlessness? ..... Yes☐ 1 No ☐

If yes . . .

a. Which medications? _____ ☐☐ ☐

b. _____ ☐☐ ☐

c. Do you take these medications ..... at the onset of the attack? ☐

only when the attack becomes more severe? ☐

48. Do you use corticosteroid tablets during an acute asthma attack? ..... not at all ☐

sometimes (less than 50% of the time) ☐

usually (more than 50% of the time) ☐

49. Have you had any injections to help your breathing at any time in the last 12 months? ..... Yes☐ 1 No ☐

If yes . . .

a. Which medications? ..... epinephrine ☐

~~immunotherapy ☐~~

other ☐

50. Have you used any other remedies to help your breathing at any time in the last 12 months? ..... Yes☐ 1 No ☐

If yes . . .

a. Which remedies? _____ ☐☐

b. _____ ☐☐

51. Have you used a peak flow meter in the last year? ..... Yes☐ 1 No ☐

52. When you are prescribed medication for your breathing . . .

a. Do you normally take (CHECK ONE BOX) ..... all of the medication as prescribed? ☐

most of the medication? ☐

some of the medication? ☐

none of the medication? ☐

b. When your breathing gets worse, and you are prescribed medication for your breathing, do you normally take.....all of the medication as prescribed? ☐
most of the medication? ☐
some of the medication? ☐
none of the medication? ☐

53. Do you think it is bad for you to take medication all the time to help your breathing? .....Yes☐ 1 No ☐

54. Do you think you should take as much medicine as you need to get rid of *all* your breathing problems? .....Yes☐ 1 No ☐

55. How confident are you that when you use medications they will work? ..... very confident ☐
confident ☐
not very confident ☐

Physician

56. Is your primary asthma care provider .....an asthma specialist (allergist or pulmonologist)? ☐
an non-asthma specialist ? ☐
not a physician? ☐

Coding ↓ ↓ < KP NOT on LIST 99980
NOT KP OR 99990
DONT KNOW 99999

a. What is that person's name? _____ ☐☐☐☐ (multiple names – draw line through boxes)
b. When were you last seen? ___/___/___ mo. day year
which clinic? _____ (do not code)

57. Have you ever been seen by an asthma specialist? ..... yes, once ☐
yes, more than once ☐
no ☐

If yes . . .
a. What is that person's name? _____ ☐☐☐☐
b. When were you last seen? ___/___/___ mo. day year
c. Name of clinic: _____ ☐

58. Have you ever been seen by a naturopath, chiropractor, or acupuncturist for asthma? .....Yes☐ 1 No ☐

59. When was the last time you were seen by a doctor because of breathing problems or because of shortness of breath?..... within last 7 days ☐
more than 7 days ago but within last 4 weeks ☐
more than 4 weeks ago but within last 12 months ☐
more than a year ago ☐

02 " " Q57
03 KP not listed S6 or S7
04 KP DON'T KNOW
05 NOT KP
06 DON'T KNO

a. Who were you seen by? ..... specialist ☐
non-specialist ☐
don't know ☐

1. What was that person's name? _____ ☐

b. Where were you seen? ..... office ☐
walk-in (UCC) or emergency room ☐
hospital ☐

60. Have you ever spent a night in a hospital because of breathing problems? ..... Yes ☐ 1 No ☐

If yes . . .

a. How many times in the last 12 months? _____

61. Have you ever visited an urgency care clinic because of breathing problems? . Yes ☐ 1 No ☐

62. Have you ever visited an emergency room because of breathing problems? .... Yes ☐ 1 No ☐

If yes . . .

a. Did you take medication before the trip?
(CHECK ALL THAT APPLY)

(if don't know, draw a line through all boxes)

aminophylline ☐
beta agonist ☐
corticosteroid ☐
epinephrine ☐
atrovent ☐
no medication ☐
other ☐

63. Do you think if you used medications appropriately there would be a lower chance of going to the ER or the hospital? ..... Yes ☐ 1 No ☐

About your health

64. In general, how would you rate your health? ..... excellent ☐
good ☐
fair ☐
poor ☐

65. Compared to one year ago, how would you rate your health now (in general)? ..... much better now than one year ago ☐
somewhat better now than one year ago ☐
about the same ☐
somewhat worse now than one year ago ☐
much worse now than one year ago ☐

67. The following questions are about activities you might do during a typical day. Does **your health** limit you in these activities? If so, how much?

	Yes, Limited a Lot	Yes, Limited a Little	No, Limi at A
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐
c. Lifting or carrying groceries	☐ 1	☐ 2	☐
d. Climbing **several** flights of stairs	☐ 1	☐ 2	☐
e. Climbing **one** flight of stairs	☐ 1	☐ 2	☐
f. Bending, kneeling, or stooping	☐ 1	☐ 2	☐
g. Walking **more than a mile**	☐ 1	☐ 2	☐
h. Walking **several blocks**	☐ 1	☐ 2	☐
i. Walking **one block**	☐ 1	☐ 2	☐
j. Bathing and dressing yourself	☐ 1	☐ 2	☐

68. During the **past 4 weeks**, have you had any of the following problems with your work or other daily activities **as a result of your physical health**?

	Yes	N
a. *Spent less time* than you would like on work or other activities	☐ 1	☐
b. *Accomplished less* than you would like	☐ 1	☐
c. Were limited in the *kind* of work or other activities	☐ 1	☐
d. Had *difficulty* performing work or other activities (for example, it took extra effort)	☐ 1	☐

69. During the **past 4 weeks**, have you had any of the following problems with your work or other daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	N
a. **Spent less time** than you would like on work or other activities	☐ 1	☐
b. **Accomplished less** than you would like	☐ 1	☐
c. Didn't work as **carefully** as you would like	☐ 1	☐

70. During the past 4 weeks, to what extent have your physical health or emotional problems interfered with your social activities with family, friends, neighbors, or groups?

☐ not at all
☐ slightly
☐ moderately
☐ quite a bit
☐ extremely

71. How much bodily pain have you had during the past 4 weeks?

☐ none
☐ very mild
☐ mild
☐ moderate
☐ severe
☐ very severe

72. During the past 4 weeks, how much did pain interfere with your work and other daily activities? .....

- not at all ☐
- a little bit ☐
- moderately ☐
- quite a bit ☐
- extremely ☐

73. These questions are about how you feel and how things have been with you during the **past 4 weeks.** For each question, check the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks:**	**All of the Time**	**Most of the Time**	**A Good Bit of Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
a. Did you feel full of pep?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
b. Have you been a very nervous person?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
c. Have you felt so down in the dumps nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
d. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
e. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
f. Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
g. Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
h. Have you been a happy person?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
i. Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
j. Has your health limited your social activities (like visiting with friends or close relatives)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

74. Please choose the answer that best describes how **true** or **false** each of the following statements is for you.

	Definitely True	**Mostly True**	**Not Sure**	**Mostly False**	**Definitely False**
a. I seem to get sick a little more easily than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

75. For each item below, check which answer best describes how often you felt this way **during the past week.**

DURING THE PAST WEEK:	**Rarely or None of the Time** (less than 1 day)	**Some or a Little** (1-2 days)	**Occas-ionally** (3-4 days)	**Most o All of the Tim** (5-7 days)
I felt depressed.	☐ 1	☐ 2	☐ 3	☐ 4
My sleep was restless.	☐ 1	☐ 2	☐ 3	☐ 4
I enjoyed life.	☐ 1	☐ 2	☐ 3	☐ 4
I had crying spells.	☐ 1	☐ 2	☐ 3	☐ 4
I felt sad.	☐ 1	☐ 2	☐ 3	☐ 4
I felt that people disliked me.	☐ 1	☐ 2	☐ 3	☐ 4

76. In the past year, have you had 2 weeks or more during which you felt sad, blue, or depressed, or lost pleasure in things that you usually cared about or enjoyed? ..... Yes☐ 1 No ☐

77. Have you had **2 years** or more in your life when you felt depressed or sad most days, even if you felt okay sometimes? ..... Yes☐ 1 No ☐

If yes . . .

Have you felt depressed or sad much of the time in the past year? ..... Yes☐ 1 No ☐

Woolcock quality of life measures

78. What follows is a series of statements describing the way in which asthma (or its treatment affects some people. You are asked to check the response to each statement that closely applies to you over the past four weeks. The following response options apply to each question: "not at all", "mildly", "moderately", "severely" and "very severely."

	not at all	**mildly**	**moderately**	**severely**	**ver severe**
a. I have been troubled by episodes of shortness of breath	☐ 1	☐ 2	☐ 3	☐ 4	☐
b. I have been troubled by wheezing attacks	☐ 1	☐ 2	☐ 3	☐ 4	☐
c. I have been troubled by tightness in the chest	☐ 1	☐ 2	☐ 3	☐ 4	☐
d. I have been restricted in walking down the street on level ground or doing light housework because of asthma	☐ 1	☐ 2	☐ 3	☐ 4	☐
e. I have been restricted in walking up hills or doing heavy housework because of asthma	☐ 1	☐ 2	☐ 3	☐ 4	☐
f. I have felt tired or a general lack of energy	☐ 1	☐ 2	☐ 3	☐ 4	☐

		not at all	mildly	moderately	severely	ve seve
g.	I have been unable to sleep at night	☐ 1	☐ 2	☐ 3	☐ 4	☐
h.	I have felt sad or depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐
i.	I have felt frustrated with myself.....	☐ 1	☐ 2	☐ 3	☐ 4	☐
j.	I have felt anxious, under tension or stressed	☐ 1	☐ 2	☐ 3	☐ 4	☐
k.	I have felt that asthma is preventing me from achieving what I want from life	☐ 1	☐ 2	☐ 3	☐ 4	☐
l.	Asthma has interfered with my social life	☐ 1	☐ 2	☐ 3	☐ 4	☐
m.	I have been limited in going to certain places because they are bad for my asthma	☐ 1	☐ 2	☐ 3	☐ 4	☐
n.	I have been limited in going to certain places because I have been afraid of getting an asthma attack and not being able to get help.....	☐ 1	☐ 2	☐ 3	☐ 4	☐
o.	I have been restricted in the sports, hobbies or other recreations I can engage in because of my asthma.....	☐ 1	☐ 2	☐ 3	☐ 4	☐
p.	I have felt generally restricted.....	☐ 1	☐ 2	☐ 3	☐ 4	☐
q.	I have felt that asthma is controlling my life.....	☐ 1	☐ 2	☐ 3	☐ 4	☐
r.	I have been worried about my present or future health because of asthma.....	☐ 1	☐ 2	☐ 3	☐ 4	☐
s.	I have worried about asthma shortening my life	☐ 1	☐ 2	☐ 3	☐ 4	☐
t.	I have felt dependent on my asthma sprays.....	☐ 1	☐ 2	☐ 3	☐ 4	☐

Demographics

79. Marital Status? ..... Never married ☐
Married ☐
Separated or divorced ☐
Widowed ☐

80. Education: Years of regular school completed.
(CHECK HIGHEST LEVEL COMPLETED ONLY)

grades 0-8 ☐
grades 9-11 ☐
high school ☐
some college ☐
college graduate ☐
post-college work ☐

81. Primary Employment Status (CHECK ONLY ONE)

employed ☐
homemaker ☐
retired ☐
unemployed ☐
student ☐
disabled ☐
other _____ ☐

82. Which of the following socioeconomic groups would you say best describes you? ..... upper class ☐
upper middle ☐
middle ☐
working ☐
lower ☐

83. Here is a list of different yearly income groups. Which group comes closest to the total amount that all members of the household combined received last year from all sources before taxes? .....

less than $4,999 ☐ 1	$30,000-$34,999 ☐
$5,000-$9,999 ☐ 2	$35,000-$39,999 ☐
$10,000-$14,999 ☐ 3	$40,000-$49,999 ☐
$15,000-$19,999 ☐ 4	$50,000-$59,999 ☐
$20,000-$24,999 ☐ 5	$60,000-$69,999 ☐
$25,000-$29,999 ☐ 6	$70,000 and more ☐

84. Would you characterize your race as ..... Caucasian ☐
Hispanic ☐
American Indian ☐
Asian ☐
African ☐
African-American ☐
other: _____ ☐

Thank You!

Today's Date: ___/___/___
mo. day year

DS 4289 z|z4|93

Study ID#_____

Allergy Testing Protocol

1	9
2	10
3	11
4	12
5	13
6	14
7	15
8	

1 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

2 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

☐☐ ☐☐ positive control _____

3 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

4 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

5 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

6 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

7 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

8 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

9 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

10 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

11 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

12 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

☐☐ ☐☐ negative control _____

13 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

14 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

15 ☐☐ 1st diam ☐☐ 2nd diam Pseudopodia? ....Yes☐ 1 No ☐

* Coding: Line through boxes if No response & can leave "pseudopodia"

APPENDIX G

Coding Data

MASTER LIST
REMEDIES:::

01 Acupuncture
02 Chiropractor
03 Exercises - breathing
04 Exercises - physical

05 Herbal
06 Homeopathy
07 Hydrotherapy
08 Kinesthesiology
09 Massage

10 Meditation
11 Naturopathy
12 Ointments,rubs,Vicks
13 Relaxation
14 Reflexology

15 Showers - hot
16 Showers - cold
17 Steam - hot
18 Steam -cold(humidify)
19 Therapy - group, psychiatric.
20 Cough syrups
21 Hot water soak(feet)
22 Cool air
23 Hot drinks
24 Coffee
25 Marijuana
26 Pillows
27 Saline
28 Vitamins
29
30 Methotrexate
31
32
33
34
35

50 Other

ASH FOOD ALLERGY CODING PAGE

01 Almonds
02 Apple
03 Apricot
04 Artichoke
05 Aubertgine (Eggplant)
06 Blueberries
07 Avocado
08 Banana
09 Barley
10 Beans (butter)
11 Beans (green)
12 Beans (red,kidney)
13 Beef
14 Blackberries
15 Blue mussel
16 Brazil nuts
17 Broccoli
18 Brussel sprouts
19 Buckwheat
20 Cabbage
21 Cacao
22 Carrot
23 Cauliflower
24 Celery
25 Cheese (hard)
26 Cheese (soft)
27 Cherry
Chicken..see poultry
28 Chocolate
29 Coconut
30 Corn
31 Crab
32 Date
33 Egg
34 Fig
35 Fish (oily,Sardine)
36 Fish (White,Cod,Plaice)
Flour...see Wheat
37 Garlic
38 Gooseberry
39 Grape
40 Grapefruit
41 Hazelnut
42 Herring
43 Kiwi
44 Lamb
45 Leek
46 Lemon
47 Lime
48 Lobster
49 Leachi
50 Malt
51 Mango
52 Melon
53 Milk(cow,similac)
54 Oat
55 Onion
56 Orange
57 Oyster
58 Papaya
59 Parsley
60 Passion fruit
61 Pea
62 Peach
63 Peanut/butter
64 Pear
65 Pecan
66 Pepper(red/green)
67 Pineapple
68 Plum
69 Pork
70 Potato
71 Poultry(ch,du,tur)
72 Pumpkin
73 Radish
74 Raspberry
75 Rhubarb
76 Rice
77 Rye
78 Salmon
79 Shrimp (Prawn)
80 Soya
81 Spinach
82 Strawberry
83 Swede
84 Tomato
85 Tuna
91 Yeast(bakers)
92 Yogurt
93 Wheat
94 Walnut
95 Tangerine
96 Mustard
101 Alcohol
102 Wine (red)
103 Wine (white)
104 Alfalfa Sprouts
105 Dried Fruit
106 Milk (goats)
107 Sugar
108 Ice Cream
109 Dairy Products
110 Yellow Dye #5
111 M S G
112 Sulfites
113 Shellfish
114 Mexican food
115 Maraschino cherries
116 Caffeine
117 BabyFormula
118 Lettuce
119 Hot dog
120 Fresh Vegetables
121 Clams
122 Red Dye
123 Apple juice
124 Mushrooms
125 Chili Powder
126 Graham crackers
127 Sausage
128 Mold-aged foods
129 Beer
130 Olives
131 Cashews
132 Spicy foods
133 Popcorn
134 Artificial Sweeteners
135 Nectarines
136 Blueberries

10 - Oral Steroid Tablets/Syrups

Celestone, Decadron, Dexasone, Hexadrol, Medrol, Predate, Deltasone, Sterapred, Prednicen, SK-Prednisone, Aristocort (BETAMETHASONE, DEXAMETHASONE, METHYLPREDNISOLONE, PREDNISONE, PREDNISOLONE, TRIAMCILONE)

11 - Oral Methylxanthines

Aminophyllin, Mudrane, Somophyllinne, Brosema, Dilor, Lufyllin, Brondec Choledyl, Accubron, Aerolate, Aquaphyllin, Asbron, Bronkodyl, Constant-T Duraphyl, Elixicon, Elixophyllin, Hydroxy Compound, Labid, Lodrane, Mar Mersalyl-Theophylline, Quadrinal, Quibron, Respbid, Slo-bid, Slo-phyllin, Somophyllin, Sustaire, Synophylate, T.E.H. tablets, T.E.P. tablets, Tedral, Th dur, Theo-dur sprinkle, Theo-Organidin, Theobid, Theoclear, Theofedral, Theolair, Theon, Theophyl, Theophylline, Theospan, Theostat 80, Theovent, Theozine (AMINOPHYLLINE, DYPHYLLINE, OXTRIPHYLLINE, THEOPHYLLINE)

12 - Antihistamine Tablets

A.R.M., Actidil, Actifed, Afrin Nasal Spray, Afrinol, Alka-Seltzer Plus, AllerAct, Allerest, Amberyl,. Atarax, Atrohist, Ayr Saline Nose Drops,..Benadryl, Bromfed, Cerose, Cheracol Plus, Chexit, Chlor-Trimeton, Codimal, Comhist, Comtrex, Congesprin, Contac, Coricidin, CoTylenol, Deconamine SR, Delacort, Demazin, Dimetane, Dimetapp, Diphenhydramine, Disophrol, Dorcol, Dristan, Drixoral, Extendryl, Fedahist, 4-Way Nasal Spray, Hispril Spansule, Histaspan, Isoclor Timesule, Kronofed, Magonate, Nolahist, Nolamine, Nostrilla, Novahistine, Optimine, PBZ-Tablets, PBZ-SR, PediaCare, Percogesic Periactin, Phenergan, Polarmine, Pyrroxate, Quelidrine, Robitussin, Rondec, Ru-Tuss, Ryna, Rynatan, Rynatuss, Scot-Tussin, Seldane, Sinarest, SineOff, Singlet, Sinulin, Sinutab, St. Joseph Nighttime, Sudafed Plus, Tacaryl, Tavist, Teldrin, Temarilm Triaminic Triaminicin, Triaminicol, Trinalin, Trind, Tussionex, Tylenol Cold Medication, Ursinus, Vick's Forula 44, Vick's Nyquil, Visine Eye Drops, Vistaril

13 - Decongestant Tablets

NASAL SPRAY MEDS

14 - Antihistamine Sprays

15 - Decongestant Sprays

16 - Steroid Sprays

Beconase, Vancenase (BECLOMETHASONE)

17 - Cromolyn Sodium

Nasalcrom

ASH Medications Codes

Q. 46 & 47 Adult Questionnaire
Q. 44 &45 Pediatric Questionnaire

INHALED MEDICATIONS

Code #

01 - Inhaled Beta-2-Agonists / NEBULIZED
Proventil, Ventolin, Brethine, Bricanyl, Brethaire, Maxair Tornalate (ALBUTEROL, TERBUTALINE, PIRBUTEROL ACETATE, BITOLTEROL MESYLATE)

02 - Inhaled Non-Specific Beta Agonists
Bronkaid Mist, Primatine Mist, Medihaler, Duo-Medihaler, Medihaler-Iso, Vapc Iso, Isuprel, Norisodrine, Alupent, Metaprel, Bronkometer, Bronkosol (ADRENALINE/EPINEPHRINE, ISOPRENALINE/ISOPROTERENOL, METAPROTERENOL/ORCIPRENALINE, ISOETHARINE)

03 - Inhaled Anticholinergic
Atrovent, Antrocol, Atrohist, Di-Atro, Donnagel-PG, Donnazyme, Lomotil, Motofen, Ru-Tuss (IPRATROPIUM BROMIDE, ATROPINE)

04 - Inhaled Steroids
Beclovent, Vanceril, Decadron Respihaler, Aerobid, Aristocort, Azmacort (BECLOMETHASONE, DEXAMETHASONE, FLUNISOLIDE, TRIANCINOLINE)

05 - Inhaled Cromolyn Sodium
Intal

06 - Other Inhalers, Non-Steroid, Single Drug

07 - Other Inhalers, Compound Bronchodilators

ORAL MEDICATIONS

08 - Oral Beta-2-Agonist Tablets, Syrups
Proventil, Ventolin, Brethine, Bricanyl (ALBUTEROL, TERBUTALINE)

09 - Oral Non-Specific Beta Agonist Tablets
Primatene tablets, Metaprel, Alupent (EPHEDRINE, ISOETHARINE, METAPROTERENOL/ORCIPRENALINE)

Correct Mark ● Incorrect Marks ⊘ ⊖ ⊗

MASTER

1

~~2/1/93~~

2/18/93

4/14/93

4/20/93

5/3/93

Data hold

#27

+

38

USE NO. 2 PENCIL ONLY

START HERE

CODE LIST A

MANAGERIAL/PROFESSIONAL/EXECUTIVE

EXECUTIVE/ADMINISTRATIVE/MANAGERIAL:
01 ACCOUNTANTS/AUDITORS/FINANCIAL MANAGERS
02 ADMINISTRATORS
03 MANAGERS
04 SUPERVISORS
05 ALL OTHER EXECUTIVE/ADMINISTRATIVE/MANAGERIAL OCCUPATIONS

PROFESSIONAL SPECIALTY:
06 ARTISTS
07 BANKERS/BROKERS
08 CLERGY
09 DENTISTS
10 DIETITIAN
11 ENGINEERS
12 LAWYERS
13 MATHEMATICS/COMPUTER SCIENTISTS
14 PERFORMERS/ENTERTAINERS
15 PHARMACISTS
16 PHYSICIANS
17 PROFESSORS/INSTRUCTORS
18 PSYCHOLOGISTS/COUNSELORS
19 REGISTERED NURSES
20 TEACHERS - PRIMARY
21 TEACHERS - SECONDARY
22 VETERINARIAN
23 WRITERS/JOURNALISTS
24 OTHER HEALTH PROFESSIONAL
25 ALL OTHER PROFESSIONAL SPECIALTY OCCUPATIONS

TECHNICAL/SALES/ADMINISTRATIVE SUPPORT
26 ADMINISTRATIVE SUPPORT/CLERICAL/OFFICE HELP
27 COMPUTER OPERATORS
28 COMPUTER PROGRAMMERS
29 HEALTH TECHNICIANS
30 INSURANCE ADJUSTORS/BILL COLLECTORS
31 RETAIL SALES/CASHIERS
32 SALES-FINANCIAL/BUSINESS
33 TRAVEL AGENTS
34 ALL OTHER TECHNICAL/SALES/ADMINISTRATIVE SUPPORT OCCUPATIONS

SERVICE:
35 CLEANING/BUILDING/HOUSEHOLD SERVICE
36 FOOD SERVICE
37 HEALTH SERVICE/ASSISTANTS/AIDES
38 PROTECTIVE SERVICE
39 BARBERS/BEAUTICIANS/COSMETOLOGISTS
40 ALL OTHER SERVICE OCCUPATIONS

FARMING/FORESTRY/FISHING:
41 FARM OPERATORS/MANAGERS
42 ALL OTHER FARMING/FORESTRY/FISHING OCCUPATIONS

CRAFTSMAN/REPAIRMAN:
43 CONSTRUCTION TRADE
44 MECHANICS/REPAIRERS
45 PRECISION OCCUPATIONS
46 ALL OTHER CRAFTSMAN, REPAIRMAN OCCUPATIONS

OPERATOR/LABORER:
47 GENERAL LABORERS
48 MACHINE OPERATORS
49 TRANSPORTATION/MATERIAL MOVING
50 ALL OTHER OPERATOR/LABORER OCCUPATIONS

ALL OTHER:
51 ARMED FORCES
52 HOMEMAKERS
53 STUDENTS
54 ALL OTHERS

55 = NEVER EMPLOYED

CODE LIST B

01 AGRICULTURE/FORESTRY/FISHING
02 MINING
03 CONSTRUCTION
MANUFACTURING
04 AGRI-CHEMICAL/PESTICIDE/FERTILIZER
05 APPLIANCE MANUFACTURE
06 BOTTLING FIRMS
07 CANDY/FROZEN CONFECTIONERIES MANUFACTURE
08 CEREAL
09 COFFEE/TEA MANUFACTURE
10 COOKIE/CRACKER/BISCUIT MANUFACTURE/BAKERIES
11 COSMETIC MANUFACTURE
12 DAIRIES/CHEESE MANUFACTURE
13 DETERGENT/SOAP/CLEANING AIDS MANUFACTURE
14 FEMININE PROTECTION PRODUCTS
15 FRAGRANCE/PERFUME DESIGN/MANUFACTURE
16 HEALTH & BEAUTY AIDS MANUFACTURE
17 GRAIN COMPANIES/GRAIN MILLS
18 ORANGE JUICE MANUFACTURE
19 PAPER PRODUCTS MANUFACTURE/PAPER MILLS
20 PRINTING/PUBLISHING
21 PHARMACEUTICAL/VITAMIN MANUFACTURE
22 SALTY SNACK/POPCORN/POTATO CHIP MANUFACTURE
23 SEAFOOD/MEAT PROCESSING
24 SOFT DRINK/OTHER BEVERAGE MANUFACTURING
25 SUGAR PROCESSING
26 ANY OTHER FOOD/GROCERY MANUFACTURING/PROCESSING
27 ALL OTHER MANUFACTURING
TRANSPORTATION/COMMUNICATION/PUBLIC UTILITIES
28 BROADCAST MEDIA-RADIO/TV
29 TRUCKING/WAREHOUSING
30 ANY OTHER TRANSPORTATION/COMMUNICATION/PUBLIC UTILITIES INDUSTRIES
31 WHOLESALE TRADE-DURABLE GOODS
WHOLESALE TRADE-NONDURABLE GOODS
32 COSMETIC PACKAGING/SUPPLY
33 FOOD PACKAGING
34 FOOD ASSOCIATIONS/COOPS
35 GROCERY WHOLESALE/DISTRIBUTION
36 OTHER WHOLESALE PACKAGING
37 OTHER NONDURABLE GOODS WHOLESALE
RETAIL TRADE
38 APPLIANCE RETAIL STORES
39 RETAIL BAKERS
40 RETAIL DRUG STORES/PHARMACIES
41 MASS MERCHANDISE/DISCOUNT/DEPARTMENT STORES
42 RESTAURANTS/DRINKING ESTABLISHMENTS
43 GROCERY RETAIL/FOOD RETAIL
44 ALL OTHER RETAIL TRADE
FINANCE/INSURANCE/REAL ESTATE
45 BANKS/SAVINGS & LOANS
46 INSURANCE COMPANIES
47 ALL OTHER FINANCIAL/INSURANCE/ REAL ESTATE INDUSTRIES
BUSINESS AND REPAIR SERVICES
48 ADVERTISING
49 APPLIANCE REPAIR
50 EXECUTIVE SEARCH FIRMS
51 MARKET RESEARCH
52 ALL OTHER BUSINESS OR REPAIR SERVICE INDUSTRIES
PERSONAL SERVICES
53 EDUCATION
54 HOTELS/MOTELS/INNS
55 ALL OTHER PERSONAL SERVICES
56 ENTERTAINMENT AND RECREATION SERVICES
PROFESSIONAL AND RELATED SERVICES
57 HEALTH SERVICES
58 ALL OTHER PROFESSIONAL AND RELATED SERVICES
59 PUBLIC ADMINISTRATION/GOVERNMENT
60 NOT CLASSIFIED ABOVE

00 = NO INDUSTRY

Industry

#28

1. Please list all me
or in the armed
birth (DO NOT i

MARKING EXAMPLE

Jane

MONTH	YEAR
① Jan	19--
② Feb	4 9
● Mar	⓪ ⓪
④ Apr	① ①
⑤ May	② ②
⑥ Jun	③ ④
⑦ Jul	● ④
⑧ Aug	⑤ ⑤
⑨ Sep	⑥ ⑥
⑩ Oct	⑦ ⑦
⑪ Nov	⑧ ⑧
⑫ Dec	⑨ ●

Write the numbers in the boxe indicated

and

fill in the correspond ovals comp

2. Is this person employe

YES, full-time
YES, part-time
NO, retired - (Skip
NO, not employed

a. Which one of the c
List A best describ
occupation?

Write in the appropriate numbe from Code List A and fill in the corresponding oval completely.

b. Which one of the co
best describes the c
works for?

Write in the appropriate number from Code List B and fill in the corresponding ovals completely.

c. Write in name of com
employed by (If self-e
write in self-employe

T. CODING SHEET 24

KAISER PERMANENTE

CONFIDENTIAL

Dataset

SURVEY OF MEDICAL OFFICE VISITS

1. Have you had a visit with a physician or other provider* at a Kaiser Permanente (KP) medical office during the past few weeks?

Yes
No

IF NO, just leave the remainder of the form blank and return it. Thank you.

IF YES, please describe the **most recent** KP visit that you (person named on label above) had by answering the following questions.

Answer by checking the appropriate box(es) or completing the blank lines.

2. At which KP medical office did your most recent visit take place?

Beaverton ☐ 01
Cascade Park ☐ 02
Division ☐ 03
52nd Ave. (HAP) ☐ 04
Central Interstate (Previously Regional Office) ☐ 05
East Interstate (Previously Health Center East) ☐ 06
West Interstate (Previously Health Center West) ☐ 07

Longview ☐ 08
Mt. Scott ☐ 09
Mt. Talbert ☐ 10
Rockwood ☐ 11
Sunset ☐ 12
Vancouver ☐ 13
SALEM:
No. Lancaster ☐ 14
Oak Street ☐ 15
Skyline ☐ 16

BESS KAISER MED CTR:
Medical Offices ☐
Urgent Care ☐
Emergency Room ☐
SUNNYSIDE MED CTR:
Medical Offices ☐
Urgent Care ☐
Emergency Room ☐

Other: Non-K.P. →
Dont Know (in K.P.) →
Dont Know at all →

3. What is the name of the provider* you saw during this visit?

4. What was the approximate date of this visit (Mo./Day/Yr.)? _____

5. At approximately what time of day did the visit occur? _____ am ☐ 1 pm ☐

6. Overall, how would you rate the care and services you received during this visit?

Superb ☐
Excellent ☐
Very Good ☐
Good ☐
Fair ☐
Poor ☐
Terrible ☐

7. In general, how satisfied were you with each of the following?
Check one box for each question.

	Very Satisfied	Satisfied	Neutral	Dis-satisfied	Very Dissatisfied
A. Amount of time the provider spent with you?	☐ 1	☐ 2	☐ 3	☐ 4	☐
B. Amount of personal interest shown by the provider?	☐ 1	☐ 2	☐ 3	☐ 4	☐
C. Provider's technical competence, skill, and ability?	☐ 1	☐ 2	☐ 3	☐ 4	☐
D. OVERALL, how satisfied were you with this visit?	☐ 1	☐ 2	☐ 3	☐ 4	☐

*NOTE: Providers are physicians, podiatrists, optometrists, psychologists, nurse practitioners, physician assistants, and other health professionals with whom visits can be scheduled.

APPENDIX H

Human Subjects

KAISER PERMANENTE

April 21, 1994

Molly Osborne, M.D.
Pulmonary and Critical Care Medicine
Division - UHN-67
Oregon Health Sciences University
3181 S.W. Sam Jackson Park Road
Portland, OR 97201

The annual review materials for your study entitled "Predictors of Hospital-Based Care in Asthma (ASH)" were reviewed and accepted by the Commit for the Protection of Human Subjects at its meeting on April 20, 1994. The Committee also approved the continuation grant.

Clyde Pope, Ph.D.
Exeeutive Secretary
Committee for the Protection of Human Subjects

cc: S. Patterson
A. Glass, M.D.
M. Greenlick, Ph.D.
B. Vollmer, Ph.D. - KP Sponsor

Further information may be obtained from Sharon Patterson, Human Subjects Committee Administrator, Kaiser Permanente Center for Health Research, 3800 N. Kaiser Center Dr., Portland, Oregon 97227-1098 Telephone 335-6791 or (760 x 6791).

OREGON
HEALTH SCIENCES UNIVERSITY
3181 S.W. Sam Jackson Park Road, Portland, OR 97201-3098
Mail Code L106, (503) 494-7887 Fax (503) 494-7787
Institutional Review Board/Committee on Human Research

DATE: April 6, 1994

TO: Molly Osborne, M.D., Ph.D. UHN-67

FROM: The Committee on Human Research

SUBJECT: ORS#: 2832
TITLE: Predictors of Hospitalization for Patients with Asthma.

This confirms receipt and approval of your memo or Continuing Review Questionnaire dated/signed 3/3/94. It is our understanding that you will not be entering any more subjects but that you do not want to close the study at this time.

This study will remain active. Approval is given for one year. However, the Committee MUST review your study before you begin entering subjects again or if there are any changes to the protocol or consent form.

Thank you for your cooperation.

wp:admin 2/92