Design and Methods of the National Cooperative Inner-City Asthma Study

Herman Mitchell, PhD,1 Yvonne Senturia, MD,2 Peter Gergen, MD,3 Dean Baker, MD, MPH,4
Christine Joseph, PhD,5 Kathleen McNiff-Mortimer, MPH,1 H. James Wedner, MD,6
Ellen Crain, MD, PhD,7 Peyton Eggleston, MD, MPH,8 Richard Evans III, MD, MPH,2
Meyer Kattan, MD,9 Carolyn Kercsmar, MD,10 Fred Leickly, MD,5 Floyd Malveaux, MD, PhD,11
Ernestine Smartt, RN,3* and Kevin Weiss, MD12

Summary. The National Cooperative Inner-City Asthma Study (NCICAS) was established to identify and then intervene on those factors which are related to asthma morbidity among children in the inner-city. This paper describes the design and methods of the broad-based initial Phase I epidemiologic investigation. Eight research centers enrolled 1,528 children, 4 to 9 years of age, from English- or Spanish-speaking families, all of whom resided in major metropolitan inner-city areas. The protocol included an eligibility assessment and an extensive baseline visit, during which symptom data, such as wheezing, lost sleep, changes in activities of daily living, inpatient admissions, and emergency department and clinic visits were collected. A comprehensive medical history for each child was taken and adherence to the medical regimen was assessed. Access, as well as barriers, to the medical system were addressed by a series of questions including the location, availability, and consistency of treatment for asthma attacks, follow-up care, and primary care. The psychological health of the caretaker and of the child was also measured. Asthma knowledge of the child and caretaker was determined. Sensitization to allergens was assessed by skin-prick allergen testing and exposure to cigarette smoke and the home environment were assessed by questionnaire. For more than a third of the families, in-home visits were conducted with dust sample allergen collection and documentation of the home environment, such as the presence of pets and evidence of smoking, mildew, and roaches. Urine specimens were collected to measure passive smoke exposure by cotinine assays, blood samples were drawn for banking, and children age 6 to 9 years were given spirometric lung function assessment. At 3, 6 and 9 months following the baseline assessment, telephone interviews were conducted to ask about the child’s symptoms, unscheduled emergency department or clinic visits, and hospitalizations. At this time, peak flow measurements with 2-week diary symptom records were collected. Pediatr. Pulmonol. 1997;24:237–252.

© 1997 Wiley-Liss, Inc.

Key words: asthma; children; inner-city.

1New England Research Institutes, Watertown, Massachusetts.
2Children’s Memorial Hospital, Chicago, Illinois.
3National Institute of Allergy and Infectious Disease (National Institutes of Health, Bethesda, Maryland).
4Mount Sinai School of Medicine, New York, New York (now at Center for Environmental and Occupational Health, University of California, Irvine).
5Henry Ford Hospital, Detroit, Michigan.
6Washington University School of Medicine, St. Louis, Missouri.
7Albert Einstein College of Medicine, Bronx, New York.
8Johns Hopkins School of Medicine, Baltimore, Maryland.
9Mount Sinai School of Medicine, New York, New York.
10Case Western Reserve University, Cleveland, Ohio.
11Howard University College of Medicine, Washington, DC.
12National Institute of Allergy and Infectious Disease (National Institutes of Health, Bethesda, Maryland) (now at Center for Health Services Research, Rush Primary Care Institute, Chicago, Illinois).


*Correspondence to: Ernestine Smartt, RN, DAIT, NIAID, NIH, Solar Building, Room 4A42, 6003 Executive Boulevard, Bethesda, MD 20892-7640.

Received 23 April 1996; accepted 16 June 1997.
INTRODUCTION

Background and Rationale

Asthma is one of the most common chronic diseases of childhood. Data from the U.S. National Health Interview Survey in 1990 indicate that nearly 3.7 million children ages 17 years or less suffer from asthma, which constitutes 5.8% of the U.S. population. Since the early 1980s asthma mortality and morbidity have increased in the United States. Asthma prevalence increased by approximately 38% among children less than 18 years of age during the 1980s. Although asthma deaths are still infrequent, asthma mortality has increased 42% among 5–34-year-olds between 1982 and 1991, i.e., from 3.4 to 4.9 per million. In contrast, asthma hospitalizations were stable between 1982–91 at 12.8 per 10,000 in this age group. However, further analyses among children 0 to 4 years of age have shown increased asthma hospitalization rates, with African-American children experiencing double the increase of white children.

The economic costs of asthma are enormous, despite its low mortality. In 1990, the cost of asthma in the United States was estimated to be $6.2 billion. Despite the widespread assumption that asthma is a mild illness, 43% of the cost was due to emergency department (ED) use, hospitalization, and death.

Poverty is associated with elevated levels of asthma morbidity and mortality. In the 1988 Child Health Supplement of the National Health Interview study found poor children with asthma suffered more disability than non-poor asthmatics. Wissow et al. found much of the difference in black–white asthma hospitalization rates could be attributed to poverty and urbanization. Other studies in New York City, Philadelphia, and Chicago have reported urban areas with high levels of poverty and minority inhabitants have increased rates of asthma hospitalization and mortality.

Although many risk factors are known for asthma, the types and intensity of these factors do not appear to be uniform across all subpopulations in the US. Smoking, which has been associated with increased asthma severity, is higher in minorities and the poor. Indoor allergens have been recognized to play an increasingly important role in asthma. Inner-city homes have been reported to have high levels of cockroach allergen, unlike the high levels of house dust mites previously reported in middle- and upper-income homes.

Objectives of the Study

In response to the increasing awareness of the excessive burden of asthma morbidity and mortality among the poor and minorities, the National Cooperative Inner-City Asthma Study (NCICAS) was established in order to develop a comprehensive asthma intervention program aimed at reducing this burden among inner-city youths. Previously, a large number of asthma education programs have been developed, but only a few were specifically targeted at inner-city youths. NCICAS was designed as a multiphase project. The NCICAS project did not attempt to compare asthmatic children to those who did not have asthma, nor did it attempt to contrast inner-city children with asthma with asthmatic children in the suburbs. Rather, NCICAS was designed as an epidemiologic investigation of the factors associated with the high levels of asthma morbidity among inner-city children, with a secondary goal of monitoring the variations in asthma morbidity experienced by these children over the course of a year. The ultimate aim of NCICAS Phase I was to provide sufficient information to design and implement a Phase II project to reduce asthma morbidity by intervening on the identified factors in this population of inner-city asthmatics.

NCICAS Phase I focused on a variety of domains believed to be critical to asthma morbidity (Fig. 1). Specifically, NCICAS studied the home environment, psychosocial components, cultural aspects, and the socioeconomic background of inner-city children with asthma. Generally, these factors could be classified into those that relate asthma morbidity to modifiable risk factors and those that relate asthma morbidity to risk factors that cannot be modified, but may serve as markers for morbidity. Figure 1 provides a schematic representation of the overall model for identifying asthma risk factors among children in the inner-city.

METHODS

Overview of the Study Design

Eight research centers (see Table 1) enrolled 1,528 children between the ages of 4 and 9 years, all of whom resided in major metropolitan inner-city areas. Population recruitment began in November 1992. Baseline as-
Assessments began in December 1992 and continued through October 1993. The protocol included an eligibility assessment, a baseline visit, a 3-, 6-, and 9-month telephone call to assess morbidity and utilization, peak flow diary recording, and for approximately 75 families per site, a home visit.

The eligibility assessment conducted during recruitment consisted of a brief interviewer-administered form given in an ED room or clinic. The methods for selecting potential subjects are described in detail in the following section. The baseline visit was conducted 3–5 weeks after the eligibility assessment. During this extensive visit, the caretaker and child were asked about adherence to medications, self-management of their asthma, health care access, psychological adjustment, and demographic characteristics. The participants were asked to recall the child's asthma symptoms and functional status during the prior two weeks and were asked for a three-month recall of utilization and school days missed. Urine specimens were collected for cotinine assessment and allergy skin testing and pulmonary function spirometry tests were performed. An optional blood draw was performed for banking. A total of 1,528 baseline interviews were conducted across the eight Asthma Study Units (ASUs).

The home visit was scheduled during the period between the baseline visit and the three-month interval assessment telephone call. During the home visit, dust samples were collected from the child’s bedroom/sleeping area, kitchen, and TV/living room. These samples were analyzed for cockroach, dust mite, and cat allergen concentrations. A trained technician completed a standardized form concerning the quality and characteristics of the living space, the building structure, and recorded general observations on cleanliness and evidence of smoking and pets in the home. A target of 75 home visits per ASU was set, for an expected total of 600. Most ASUs were able to exceed the target number, resulting in 663 home visits.

The follow-up telephone contacts involved a series of two calls: the first to initiate peak flow diary recording and the second to obtain an interval assessment of asthma symptoms.

### Table 1—NCICAS Recruitment Sites

<table>
<thead>
<tr>
<th>ASU</th>
<th>Number of ED sites</th>
<th>Number of clinic sites</th>
<th>Total participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baltimore</td>
<td>2</td>
<td>2</td>
<td>159</td>
</tr>
<tr>
<td>Bronx</td>
<td>1</td>
<td>1</td>
<td>212</td>
</tr>
<tr>
<td>Chicago</td>
<td>1</td>
<td>5</td>
<td>238</td>
</tr>
<tr>
<td>Cleveland</td>
<td>1</td>
<td>2</td>
<td>191</td>
</tr>
<tr>
<td>Detroit</td>
<td>1</td>
<td>1</td>
<td>157</td>
</tr>
<tr>
<td>New York</td>
<td>1</td>
<td>5</td>
<td>184</td>
</tr>
<tr>
<td>St. Louis</td>
<td>2</td>
<td>4</td>
<td>211</td>
</tr>
<tr>
<td>Washington, D.C.</td>
<td>3</td>
<td>5</td>
<td>176</td>
</tr>
</tbody>
</table>

**Total** 13 25 1,528
symptoms. The interval assessments were targeted for 3, 6, and 9 months after the baseline visit, with the reminder calls to initiate peak flow diary recording two weeks prior to the target date for each interval assessment. Nearly all interviews were conducted by telephone; however, for some hard-to-reach participants the staff went out in the community and completed interviews in person. The interviews took about 10 minutes to administer and included primarily the same morbidity and utilization questions asked at baseline. Telephone interviewers updated all phone and address information for the participants and their alternate contacts during each interview contact. This repeated updating of contact information helped contribute to the high completion rates of 91%, 92%, and 95% (of the initial sample) for the 3-, 6-, and 9-month interviews, respectively.

The peak flow diary involves twice-daily recording of peak flow and asthma symptoms for two weeks after baseline and again for the two-week period just prior to each 3-, 6-, and 9-month interval assessment. Participants were encouraged to fill the diaries out accurately and avoid guessing. The percentages of peak flow diaries returned were lower than the follow-up interviews; 61% after baseline and 56%, 57%, 57%, respectively, at the 3-, 6-, and 9-month assessments. Figures 2 and 3 provide an overview of the study procedures and timelines.

This broad range of factors (demographic, access, adherence, psychosocial, home environment, atopy, pulmonary function, etc.) was examined for possible association with the child’s asthma morbidity. A number of different measures of morbidity were chosen for measurement at baseline and at each of the 3-month interval...
assessments. The primary morbidity measures included the child’s symptoms recalled for the prior two weeks (wheeze, slow play, and lost sleep due to asthma); utilization (unscheduled doctor or ED visits and hospitalizations); and impact on the caretaker (caretaker lost sleep or change of plans due to their child’s asthma).

Population

Eligibility

The target population consisted of 4–9-year-old children of English- or Spanish-speaking families who lived in selected inner-city census tracts of the eight metropolitan areas served by the NCICAS ASUs and who satisfy the NCICAS definition of asthma, as indicated below. The study group consisted of both the asthmatic child and their families, with each ASU recruiting approximately 180 children. Participants could not be enrolled in another asthma research project and were required to speak English, except for the two New York ASUs and the Chicago ASU. In the New York and Chicago ASUs, bilingual Spanish/English-speaking recruiters enrolled both Spanish- or English-speaking participants. Each ASU was required to have at least one ED and two clinic sites from which to recruit study participants.

Definition of Asthma

Each study child was required to have asthma as defined by satisfying at least one of the following entry criteria:

1. a) Having been told by a physician that the child has asthma (or bronchitis with wheezing, or asthmatic bronchitis).

and

b) Cough, wheezing, shortness of breath, or whistling in the chest or tightness in the chest lasting for more than three days within the past 12 months.

OR

2. Cough, wheezing, or shortness of breath, that lasted more than six weeks during the last 12 months and meeting three out of the five following criteria:

a) cough, wheezing, or shortness of breath was present more than half the days and nights during the 6-week period;

b) cough, wheezing, or shortness of breath was aggravated by exercise or cold air;

c) a parent or sibling with asthma;

d) no history of antibiotic therapy for sinusitis accompanying the cough;

e) cough, wheezing, or shortness of breath that resulted in disturbance of the child’s sleep.

It should be noted that this definition of asthma does not require a physician diagnosis of asthma and, consequently, 9.5% of the NCICAS-recruited population did not have a prior physician diagnosis of asthma.

Criteria for Defining Severity at Entry

In order to ensure that the NCICAS population had sufficient symptoms and severity to permit identification of related factors, the project attempted to recruit a sample in which at least 50% had a high level of morbidity in the last year. These children were designated as “severe asthmatics” in NCICAS, as defined by:

a) self-reported use of three or more classes of medicines for asthma prescribed simultaneously at some time in...
the past year (classes are: beta agonists, methylxan-
thines, corticosteroids, cromolyn);

or

b) use of daily bronchodilator therapy for six or more
months in the past year;

or

c) two or more hospitalizations for asthma, or one ICU
visit for asthma in the past year;

or

d) three or more ED visits, including the current visit, for
asthma in the past year.

Balancing Study Population Severity

To ensure that at least 50% of the sample met the
NCICAS criteria for severe asthma, recruiters were asked
to give preference to children presenting during an acute
asthma episode. Additionally, the Data Coordinating
Center (DCC) continually monitored the recruitment distri-
butions of severity by recruitment site (clinic vs. ED)
at each ASU. When the percentage of recruited children
at a particular ASU fell below the 50% level for severe
asthma, the ASU recruitment schedule was modified to
increase recruitment at those sites at the ASU producing
the most children in the severe category. This was very
seldom required and usually involved adding additional
recruitment shifts at an ED recruitment site. Of the 4,570
children screened, 2,385 met eligibility criteria, 90%
consented, and 60% of those who consented were de-

Geographic Eligibility Criteria

In order to be eligible for the NCICAS study, the
child’s primary residence had to be in an inner-city cen-
sus tract served by the ASU. An “inner-city census tract” was defined as a census tract that fulfills the fol-
lowing requirements:

1. It must be located in one of the seven Standard Me-
tropolitan Statistical Areas (SMSA) served by the
eight ASUs.
2. At least 20% or more of the households having in-
comes below the federal government’s established
poverty level for 1990.

Census tracts were employed to define the inner-city
areas because they are smaller areas than zip codes and
are defined so that they are rather homogenous with re-

Exclusion Criteria

Children and caretakers who did not speak English (or
Spanish, at the three ASUs with bilingual interviewers)
were considered ineligible. Children who were not able
to complete the study questionnaires because of physical
limitations or mental retardation were also excluded. If
consent could not be obtained from the legal guardian, as
in the case of children in foster care, they were not per-
mitted into the study. Involvement with any other
asthma-related research project was excluded for poten-
tial participants. As mentioned above, those children out-
side the geographic eligibility boundaries were excluded.
Table 2 provides details of children excluded from the
sample. No children were excluded because they were
unable to complete study forms or were under foster care.

Recruitment Procedures

The selection of recruitment sites was designed to pro-
duce a study population that encompassed a broad rep-

or
including variation in access to medical care) than would be identified using only a single hospital site. Nonetheless, even this method would miss some of those children who never access EDs or community clinics for their asthma care. To minimize this loss, every family in the EDs or clinics was approached as potential study participants regardless of the reason why they were at the ED. Referrals from friends and relatives of participants, or from physicians or other health care providers, were not allowed.

**Sampling Between Recruitment Sites**

Because it was desirable to group data from the different sites for analysis, an effort was made to balance the number of subjects from these different types of recruitment sites to facilitate the assessment of a potential “recruitment site effect.” This balance was achieved by having recruiters rotate among the sites. The target distribution of children recruited from the ED compared to community sites was intended to be approximately a 75% to 25% ratio, with a minimum of 20% from clinics. Guidelines were established so that the proportions were relatively consistent across the ASUs.

**Recruitment Protocol**

Each family identified in the sampling frame was approached by an NCICAS recruitment staff member to screen for eligibility. Interviews were conducted in the respondent’s primary language (English or Spanish), determined by the recruiter at the beginning of the interview. The child and family may have been presenting for causes other than asthma. The staff member explained that they were seeking participants for a study of children with breathing problems. The primary caretaker (or other responsible adult) was asked to respond to an eligibility questionnaire pertaining to all children in the family, not just the child presenting for care on that occasion. If more than one child in the family met the selection criteria, the index child was the child most recently symptomatic (i.e., the one with the most recent episode of wheezing or prolonged cough). Informed consent was obtained from the child’s legal guardian. While the study designed a common consent form, the Institutional Review Boards (IRB) of each ASU guided the final format of the subject consent.

Table 2 illustrates the distribution of the NCICAS study population from screening through baseline examination. All 2,385 eligible families (52% of total screened) were recruited for the study. After determining that a child was eligible, the recruiter described the NCICAS clinic and home visits, the questionnaires, the skin, pulmonary function, blood and urine testing, and the follow-up contacts. Families were told they would be reimbursed for their time and expenses, which was explained to be $50 for the baseline assessment, $20 for each interval assessment, and a $20 bonus for families

<table>
<thead>
<tr>
<th>Total</th>
<th>Acute ED</th>
<th>Nonacute ED</th>
<th>Acute clinic</th>
<th>Nonacute clinic</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screened for Eligibility</td>
<td>4,570</td>
<td>909</td>
<td>2,677</td>
<td>28</td>
<td>947</td>
</tr>
<tr>
<td>Ineligible</td>
<td>2,185</td>
<td>342</td>
<td>1,381</td>
<td>5</td>
<td>448</td>
</tr>
</tbody>
</table>

Reasons for ineligibility (available on 2,175)

1. Asthma definition | 1,164 | 56 | 834 | 1 | 273 |
2. Child’s language | 26 | 10 | 11 | 0 | 5 |
3. Enrolled in other study | 33 | 11 | 11 | 0 | 11 |
4. Address | 952 | 265 | 525 | 4 | 159 |
5. Caretaker’s language | 0 | 0 | 0 | 0 | 0 |

Eligible | 2,385 | 567 | 1,296 | 23 | 499 |

Consent not given | 242 | 57 | 139 | 1 | 45 |
Consented | 2,143 | 510 | 1,157 | 22 | 454 |
Baseline not completed | 615 | 132 | 345 | 2 | 136 |

Reasons for deactivation

1. Could not contact | 225 | 53 | 126 | 1 | 45 |
2. Incorrectly enrolled | 21 | 3 | 15 | 0 | 3 |
3. Noncompliant | 290 | 62 | 159 | 0 | 69 |
4. Other | 79 | 14 | 45 | 1 | 19 |
Completed baseline | 1,528 | 378 | 812 | 20 | 318 |

1 Percent of total screened.
2 Percent of total eligible.
3 Percent of consented and eligible.
completing all scheduled interval assessments. In 90% of eligible families, the recruiter was successful in obtaining informed consent to participate. Only self-designated legal guardians were allowed to give consent. Baseline examinations were scheduled to be performed four weeks after recruitment, with an allowance of plus or minus one week, and were completed in 71% of those who consented to enroll.

A home telephone number and at least two alternate contact telephone numbers were obtained at recruitment and confirmed at baseline, along with the time of day preferred for receiving calls. The ASUs were required to reschedule a no-show (for baseline) at least two times. It was at the individual ASUs discretion whether to pursue families further after two failed appointments for two baseline evaluations.

**DATA COLLECTION**

**Pilot Procedures**

**Pretesting**

During the forms development process, interviewers at each site pilot tested the recruitment forms and baseline interview procedures. Committees responsible for each form reviewed the pilot data to determine whether the questions provided adequate response distributions and if they were understood by the participants. Revisions were made and the pilot process was repeated. After attending a centralized training session, each interviewer completed the baseline interview on several more pilot participants using the final forms.

**Ethnographic Evaluations**

The cultural committee was comprised of nurses, health educators, epidemiologists, anthropologists, and physicians and they reviewed the forms for cultural biases and literacy level. Modifications were made whenever possible. However, several of the standardized forms were not altered, in order to preserve the psychometric properties and external validity.

**Translation**

Interviews were conducted in both English and Spanish in the Bronx, New York, and Chicago ASUs. All study forms, hand-outs, and mailings were centrally translated by professional translators. Following this translation, a Spanish-speaking representative from each site served on a subcommittee to review the materials and reach a consensus concerning standardized wording. In several instances, it was necessary to provide alternate wordings of key phrases to accommodate differences between the New York and Chicago Hispanic subpopulations.

**Substudies**

Several substudies were conducted in the EDs during the recruitment of acute asthma cases. These studies included a chart audit of all participants recruited during an acute attack and post-visit interviews with patients and providers. When possible, caretakers of children presenting with acute attacks were asked to permit audio tape-recording of the ED physician–family interaction. Methods and results of these substudies will be reported in subsequent manuscripts.

**Baseline Procedures**

**Baseline Interview**

Before the baseline interview began, each caretaker was screened for literacy by completing a brief survey about his or her neighborhood. If the participant was unable or unwilling to complete the brief literacy survey, the baseline interview was administered orally and responses were recorded by the interviewer. Those participants with a sufficiently high literacy level were given the option of self-administering several of the standardized instruments. Whenever possible, the child and adult interviews were conducted in separate rooms, although the caretaker was present for the child’s pulmonary testing, blood draw, and skin testing.

The baseline day included an extensive questionnaire interview about asthma morbidity and potential risk factors. Symptom data, including wheezing, lost sleep, and reduction in play activity due to asthma were collected for the two weeks prior to the baseline interview. Missed days of school (for the child) and work (for the caretaker) as well as inpatient admissions and visits to an ED or clinic were collected for the previous three months. Questions regarding the child’s current and previous health status included maternal age at birth, prematurity, ICU or respirator at birth, breast feeding, and other medical conditions including allergies, hay fever, and bronchitis. Adherence to a medical regimen was assessed by collecting the names and dosage of medicines used, information regarding filling of prescriptions, avoidance of triggers, emergency plan, belief about side effects, use of devices such as peak flow meters, nebulizers, mattress covers, and problems giving medicines at home or school. Asthma knowledge of the child and caretaker was determined by administering a modified version of the Open Airways asthma knowledge questionnaire. Information was also obtained on home environmental conditions, sensitization to indoor and outdoor allergens, and passive exposure to cigarette smoke in the child’s home. The primary caretaker was asked to report on the kind of building (e.g., detached house, apartment, etc.); main heating sources; presence of central air conditioning; use
of gas for cooking or heating; and the presence of windows, moisture or leaks, carpeting, and household pets.

Access to the medical system was assessed by a series of questions, including the location, availability, and consistency of treatment for asthma attacks, follow-up care, and primary care. For each of these aspects of care, participants were asked to identify barriers, such as lack of insurance, financial concerns, transportation, and language problems. The psychological health of the primary caretaker was measured by administering the Brief Symptom Inventory, PERI Life Events, CAGE, and a modified social support instrument. The child’s psychological status was measured by the Achenbach Child Behavior Check List. Psychosocial measures are described in detail in the accompanying article in this issue of *Pediatric Pulmonology* by Wade et al. 33

**Skin Testing for Sensitization to Indoor and Outdoor Allergens**

During the examination, the child’s atopic status was assessed with multi-skin puncture tests. The antigens chosen include those most commonly addressed in atopic subjects, as well as antigens to which inner-city children are likely to be sensitized. Skin testing was done by puncture using the Multi-Test device, which allows the tester to apply eight antigens simultaneously. All children had skin testing performed with the following allergens: dust mites (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*), cat, dog, rat, mouse, cockroach, *Alternaria, Penicillium*, timothy grass, orchard grass, oak, maple, ragweed, negative (diluent) control, and positive (histamine) control. All extracts were standardized extracts of 10,000 Allergy Units (AU) per ml. One panel was applied to the volar surface of each arm. Tests were read after 15 minutes by measuring the wheal for each antigen and for the controls. Skin tests were considered valid only if the difference in wheal diameter between positive control and negative control was greater than 1 mm. Sensitivity to an allergen was considered positive when the difference in wheal diameter between the particular allergen and negative control was greater than 2 mm.

**Urine Cotinine Measures of Passive Smoking**

Children were asked to provide urine samples for cotinine measurement as an indicator of recent exposure to cigarette smoke. Urine samples were collected using disposable urine cups. The samples were refrigerated within 6 hours of collection. A five-ml aliquot of each sample was transferred into a labeled screw-top tube and frozen within 24 hours of collection. The vials were subsequently shipped on dry ice to a central laboratory for analysis. The urine samples were analyzed for cotinine content using a monoclonal antibody-based competitive ELISA as reported by Langone et al. 1,14 The results were reported as nanograms of cotinine per milliliter of urine. Creatine was assayed by the Allergy Research Laboratory Henry Ford Hospital. A total of 1,330 children provided specimens.

**Blood Draw**

A single 5 ml sample of whole blood was drawn from each of the consenting study participants. The blood was separated into sera and clot which were stored under appropriate conditions such that the sera could be used for in vitro assays of allergic sensitivity and the clot may provide material for future molecular (DNA) studies. The 5 cc vacutainer tube was allowed to clot at room temperature for 30 minutes or longer, but not to exceed 120 minutes. The tube was then opened and the clot ‘rimmed’ using a disposable transfer pipette. The tube was centrifuged at 800 × g or greater for 30 minutes. The sera was removed and transferred to a polypropylene snap-cap tube using a plastic or glass transfer pipette. The clot was dislodged from the vacutainer tube and transferred to a second polypropylene snap-cap tube.

Each tube was labeled using the foil back label with preprinted study IDs. The tubes containing sera were frozen and stored at −30°C or below until shipped in dry ice to central storage. The tubes containing the clot were stored at −70°C or lower until shipment.

**Pulmonary Function**

In order to assess pulmonary function of study participants, spirometry and measurement of peak flow were performed during the baseline encounter. Although children age 4–9 years were eligible for study, forced spirometry maneuvers were limited to subjects 6–9 years of age. Peak flow measurements were performed on all children aged 4–9 and caretakers were asked to keep a 2-week diary of peak flow measures and respiratory symptoms.

A 12 L dry-sealed spirometer connected to a personal computer and an analog to digital interface was used for all forced expiratory spirometry maneuvers (Pulmo-Screen II/EVRS; S&H Instrument, Doylestown, PA). Software allowed the entry of study identifiers and patient demographics and utilized American Thoracic Society “end of test” criterion with a maximum maneuver duration of 15 seconds. ATS criteria were modified for children to extract information from either FEV₁ or FVC when complete ATS criteria were not met. We accepted FVCs of 4-second duration rather than 6 seconds, or when a clear plateau was reached after 3 seconds. Also, FEV₁ levels were used for analyses in some instances when FVC criteria were not met, provided visual inspection of flow volume curves indicated the performance of a maximal effort with no hesitation. Standard prediction
equations were used along with the appropriate ethnic adjustments.\textsuperscript{15}

Technicians from each NCICAS site were centrally trained for pulmonary function testing. Each technician completed a one-day training course in spirometric testing designed to certify them for NCICAS pulmonary function assessments. The course was a shortened version of that approved by the National Institute of Occupational Safety and Health (NIOSH) for occupational spirometric testing. After training, pulmonary function technicians were required to perform at least 10 maneuvers prior to the onset of baseline interviews at their own site. Hardcopies of these maneuvers were sent to an NCICAS pulmonologist who then provided feedback to each of the technicians.

Forced vital capacity (FVC) maneuvers were conducted for children ages 6–9 years. Pulmonary function technicians were instructed to procure a minimum of three acceptable tests (two of which were reproducible within 85–90\%) and, in doing so, to allow for no more than eight attempts before administration of the bronchodilator. After satisfactory completion of the initial pulmonary function maneuvers, a bronchodilator medication (albuterol sulfate inhalation solution 0.083\%) was administered by nebulizer. Spirometry was repeated 10 minutes after the start of nebulization. Research staff attempted to obtain three satisfactory FVC post-bronchodilator maneuvers without exceeding five attempts. Children presenting in obvious distress, e.g., persistent cough, wheeze, or inability to speak, were not asked to perform pulmonary function maneuvers. Pulmonary function testing was terminated when lung function levels decreased $\geq20\%$ from that of the initial maneuver, or if the child developed symptoms of wheeze, persistent cough, shortness of breath, or otherwise appeared in distress.

To monitor quality control, on-site pulmonary function specialists were enlisted to evaluate every tenth pulmonary function maneuver performed by NCICAS personnel. Spirometer calibration, leak, and volume checks were performed daily, prior to onset of pulmonary function testing. Calibration was achieved using a 3-liter syringe and standard recommended procedure. Results were stored on the hard disk and then uploaded to the NCICAS clinic computer. Hardcopies of flow-volume curves were mailed to the NCICAS data coordinating center on a weekly basis. Clean breathing hoses were used for each participant.

**Peak Flow Measurement**

Mini-Wright\textsuperscript{®} peak flow meters were used for the peak flow assessment. Research staff presented a peak flow meter to the caretaker and demonstrated its use. The child was asked to practice using the peak flow meter in the caretaker’s presence until research staff were satisfied that the child was performing the procedure correctly, and that the caretaker was comfortable with the procedure and diary. The highest of three readings was recorded on the peak flow diary. Caretakers were instructed to follow whatever guidelines a doctor or health care provider may have given regarding the child’s asthma treatment should the peak flow fall or register very low.

**Peak Flow Diaries**

Caretakers were asked to record peak flow and symptoms in a diary twice per day for a period of 2 weeks. The first 2-week period began on the day of the baseline visit. Additional 2-week periods followed at 3, 6, and 9 months post-baseline for a total of four peak flow diary recording periods. In addition to the peak flow rate, diaries had spaces to record the presence or absence of respiratory symptoms, i.e., chest tightness, shortness of breath (unable to breathe), cough, wheeze, fever, and runny/stuffed nose. Caretakers were instructed to note the child’s symptoms by observation or by asking the child and record the information. Caretakers performed the peak flow and symptom assessment in the morning and again at the child’s bedtime, prior to administration of any inhaled medications.

Caretakers were given a stamped envelope, addressed to the ASU, for return of the completed peak flow diary. Research staff were instructed to emphasize the necessity of accuracy in keeping the diary and to have the caretaker avoid “guesses” should the caretaker forget to have the child use the meter, or forget to record flow rates and symptoms. To discourage random completion of the peak flow diary, study incentives were not contingent on their return. Caretakers were also instructed to always measure the peak flow prior to administration of an inhaled bronchodilator in the morning or at bedtime.

**Environmental Home Visits**

**Home Visits**

Home visits were conducted by trained study staff on 75 children at each ASU to assess home environmental conditions and obtain objective measurement of household dust antigen concentration and nitrogen dioxide air concentration. The size of this subsample was based on budget considerations and estimates of statistical power, which indicated that this sample size was adequate to show expected differences for these measures. Families were recruited for home visits at the time of baseline evaluation, with these visits scheduled within one month after baseline. During the visit, the technician completed a standardized home inspection concerning the quality and characteristics of the building structure and recorded observations on the household environmental conditions and habits of residents. Specimens of dust to be analyzed for antigen concentration were obtained by vacuuming in
three rooms. A Palmes tube to measure average nitrogen dioxide concentration was placed in the child’s bedroom, to be returned by the family by mail after one week of passive air sampling.

The potential danger of physical assault to NCICAS staff was addressed by scheduling home visits during daylight hours, by visiting in teams of at least two persons, by calling before the visit to carefully coordinate home access, timing, parking, etc., with the family to be visited, and by providing safety training sessions for staff members. Whenever possible, staff for home visits were recruited from the inner-city neighborhoods. The danger of allergen sensitization and symptom induction among NCICAS staff during household dust collection and sample processing was addressed by educating staff regarding the risks, by providing staff with dust protection masks, and by maintaining full room ventilation during sample handling.

The home inspection form was completed by the technician based on direct observation of the household. For some questions, such as the age of the structure or functioning of a vacuum cleaner, the technician asked the present family members. General information recorded during the inspection included type of dwelling (e.g., detached house, apartment, etc.); age of structure; general state of disrepair; type of subfloor and basement; heating and cooling sources; use of appliances such as vacuum cleaner, washing machine and dryer; and presence of pets in the household. Many of the inspection items corresponded to questions asked during the baseline examination so that the correlation between these data sources could be evaluated during data analysis. The family/TV room, child’s bedroom (or primary sleeping area), and the kitchen were inspected for evidence of moisture or leaks; mildew; musty smell; cigarette smoke or butts; windows (and whether they could open); window and floor coverings; type of furniture; and evidence of cockroach stains or mouse droppings. The child’s bed mattress and pillow encasement were also examined.

**Dust Collection**

The study measured two dust mite allergens (der p I and der f I) as well as cat (fel d I) and cockroach (bla g I) allergens. Each of these allergens is associated with a high prevalence of IgE-dependent sensitization in clinical surveys of allergic populations. Moreover, for each one the major allergen has been identified and purified. In addition, assays are available that allow the antigens to be quantified in household dust samples.

Sampling utilized Douglas Redivac (Model # 6735) hand-held portable vacuum cleaners. Samples were collected in three sites: the child’s bedroom and bed, the family or TV room, and the kitchen. A separate vacuum filter was used to sample each of the sites. In the bedroom, a one (1) square meter area of the floor near and underneath the bed was vacuumed for 2 minutes, as was any stuffed furniture found in the bedroom. To collect the sample from the bed, bedding was removed and the mattress surface (or the surface of the plastic mattress cover) was vacuumed for 2 minutes. In the TV room, a site approximately in the center of the room was selected and a 1 square meter area of the floor was sampled for 2 minutes using a template. In addition, stuffed furniture in the TV room was vacuumed for an additional 2 minutes using the same vacuum and the same filter that was used on the floor in that room. In the kitchen, the entire floor was vacuumed for 4 minutes, with particular attention to the base of counters and the interior of the under-sink cabinets. If possible, dust behind and underneath the refrigerator was brushed off with a small brush and vacuumed. After each room sampling, the filter was removed and sealed in separate plastic bags. After each home visit, the inside of the front nozzle of the Douglas Redivacs® was washed with 120°F water and a detergent for 30 seconds or more, then rinsed thoroughly with tap water and dried before a new filter was installed. The bagged filters were labeled, stored at −10°C, and later sent in batches to the Johns Hopkins laboratory using overnight courier service.

In the laboratory, the dust was brushed off the filter onto a 0.3 mm brass sieve. Sieved specimens were weighed and stored in glass vials at −20°C. Later, specimens were thawed and a 100 mg aliquot was extracted for 2 hours in a cold room with continuous rotation in 2 ml borate buffered saline, pH 8 (1:20 dilution). The aqueous extracts were stored at −20°C until analyzed.

The extracts were assayed for der p I, der f I, fel d I, and bla g using a two-site ELISA method. The assays involved overnight coating of microtiter plates (Dynatech, Alexandria VA) with 1 μg of appropriate monoclonal antibody, after which the plates were blocked with PBS-Tween-BSA. Wells were filled (100 μl) with dilutions of an antigen standard or with an unknown extract, incubated for 4 hours at 25°C, and washed again. A second biotinylated monoclonal antibody which recognizes another epitope of the same antigen was added and developed with HRP-avidin after another incubation and wash. Antigen levels were quantitated as ng/gm of dust concentrations of der p I and der f I were added and recorded as total mite antigen. Samples were quality-controlled by exchange of specimens with a second analytic laboratory.

**NO₂ Collection**

Nitrogen dioxide is an oxidant that causes lung damage at high concentrations. Although some authors have questioned the health effects of indoor nitrogen dioxide levels, a meta-analysis study suggested that typical exposure from gas cooking stoves might cause a 20% increase in respiratory symptoms. Current technol-
ogy using the Palmes tube allowed sampling to be accomplished without great expense or inconvenience during the home visit. The purpose of the Palmes tube was to measure the average concentration of nitrogen dioxide (NO₂) in the air over approximately a 7-day period. The sampler measures NO₂ by chemically reacting with the NO₂ contained in the air that passively diffuses into the sampler during the time the cap is removed.32

Questions potentially relevant to NO₂ exposure, including the presence of a gas stove, windows in the kitchen that do not open, and venting of washers and dryers inside the home were asked during the baseline examination and ascertained during the home inspection. For objective NO₂ sampling, the technicians attached a Palmes tube to the wall or furniture in the child’s bedroom or sleeping area during the home visit. The sampler was placed in a vertical orientation with the open end pointed down. The location of the sampler and time the cap was removed were recorded. The family was provided with a mailer and asked to remove the tube and send it to the center at the end of 7 days. The family member replaced the cap before mailing the tube and recorded the time the cap was replaced. The samplers were mailed to the ASU, where they were logged in and stored for no longer than two weeks. They were later sent in batches to the laboratory for analysis. A total of 526 Palmes tubes were returned and analyzed.

The samplers have a sensitivity of 600 ppb-hr. That is, any combination of exposure concentration and time multiplying to 600 ppb/hr will be analytically distinguishable from a zero reading. Similarly, any two samples differing in exposure by more than 600 ppb-hr would be statistically different from each other. For example, assuming a sampling period of 168 hours over 7 days, the samplers could detect an average NO₂ air concentration of 3.6 ppb and distinguish between two samples that differed by this amount. Standard quality control procedures were maintained with use of more than 10% laboratory blanks, field blanks, and replicate samplers for quality assurance evaluation.

Interval Assessments

A series of questions pertaining to asthma morbidity were administered by telephone at intervals of 3, 6, and 9 months after the baseline visit. In addition, the respondent was asked about changes in the primary caretaker and health insurance. Ideally, a 2-week peak flow and symptom diary was completed for the 2 weeks prior to each interview so that the verbal report of symptoms would overlap the diary recordings. Eight weeks after baseline, a letter was sent to each participant. Included in the letter was a small incentive gift, a return postcard for change of address and/or telephone number, and a peak flow diary with a stamped envelope addressed to the ASU. The letter indicated that they would be called by the ASU in approximately 2 weeks to start the diary, and called again in another 2 weeks to conduct a brief interval assessment. At the completion of the interview, the participant was asked to mail the diary directly to the ASU. If the peak flow diary was not received within 10 days of the phone assessment, a reminder call was made to the participant. Participants who completed the interviews received $20.

Analytic Procedure

The Phase I NCICAS project was a broad-based epidemiologic investigation which was undertaken to identify factors associated with morbidity among inner-city children with asthma. A variety of hypotheses and expectations regarding predictors of asthma severity within this population were suggested. Many of these hypotheses suggest rather complex multivariate models and the exact analytic plans for these various domains will be detailed in subsequent reports. In this report, the general approach to the study design and its power to detect differences between severe and mild asthmatics with regard to the many factors studied is provided.

Measures of morbidity included symptoms (wheeze, slowing play activities due to asthma, and loss of sleep due to asthma), unscheduled visits (to ED or clinics), and hospitalizations. At baseline, 3, 6, and 9 months, caretakers were asked to estimate the number of days with symptoms in the previous 2 weeks and the number of unschedules visits or hospitalizations in the previous 3 months. Data from these four time intervals were used to estimate data for the entire year. Symptoms were expressed by the average number of symptoms over a 2-week period, and utilization was expressed by the number of visits or hospitalizations in a year. Several approaches can be applied to assess the relationship of these factors with asthma morbidity; first, correlations of the factors with the child’s morbidity can be measured, and second, comparisons of these factors can be made between children with high morbidity vs. those with lower morbidity. Extensive univariate and multivariate analyses were planned to determine the relationship between these measures of morbidity and various demographic variables and risk factors. Measures of morbidity were analyzed both as continuous variables and as categorical variables (for example, low, medium, or high).

Power Assumptions

The outcomes (morbidity and utilization) and predictors in the NCICAS project include both continuous and categorical variables. Since little information was available regarding the distributional characteristics of many of these variables, statistical power was examined by considering a range of possible situations. Power was evaluated by determining the minimum difference (between high and low levels of morbidity, for example) that
could be detected with 80% power and a significance level of 5%. These calculations were performed for sample sizes of 1,200 and 1,600.

For proportions, it was assumed that an outcome of interest would be compared in two groups (for example, males and females) with sample sizes $n_1$ and $n_2$. The power of the statistical test depends on the ratio of the sample size in one group to the total sample size, $n_1/n$, and the two proportions, $p_1$ and $p_2$. It is convenient to express these proportions as a rate ratio, $p_1/n$. The following table shows the minimum detectable rate ratios for several different values of $n_1/n$ and $p_1$.

<table>
<thead>
<tr>
<th>$n_1/n$</th>
<th>$p_1$</th>
<th>$n = 1,200$</th>
<th>$n = 1,600$</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3</td>
<td>0.05</td>
<td>2.68</td>
<td>2.27</td>
</tr>
<tr>
<td>0.3</td>
<td>0.25</td>
<td>1.41</td>
<td>1.34</td>
</tr>
<tr>
<td>0.5</td>
<td>0.05</td>
<td>2.41</td>
<td>2.09</td>
</tr>
<tr>
<td>0.5</td>
<td>0.25</td>
<td>1.37</td>
<td>1.31</td>
</tr>
<tr>
<td>0.5</td>
<td>0.45</td>
<td>1.22</td>
<td>1.19</td>
</tr>
</tbody>
</table>

For a comparison of means, the difference to be detected can be expressed as the signal-to-noise ratio, which is the difference between the means divided by the within-group standard deviation. The minimum signal-to-noise ratio that can be detected for several sample size ratios is shown in the following table:

<table>
<thead>
<tr>
<th>$n_1/n$</th>
<th>$n = 1,200$</th>
<th>$n = 1,600$</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>0.27</td>
<td>0.23</td>
</tr>
<tr>
<td>0.3</td>
<td>0.21</td>
<td>0.15</td>
</tr>
<tr>
<td>0.5</td>
<td>0.19</td>
<td>0.14</td>
</tr>
<tr>
<td>0.7</td>
<td>0.21</td>
<td>0.15</td>
</tr>
<tr>
<td>0.9</td>
<td>0.31</td>
<td>0.23</td>
</tr>
</tbody>
</table>

Quality Control Observations

At the start of the study, principal investigators and project coordinators reviewed study procedures and observed techniques for spirometry and skin testing. Throughout the course of the study, quality control observers monitored spirometry and skin testing technique. Quality control monitoring forms were completed and sent to DCC for review by both DCC and the NIAID project office.

Protocol Monitoring

During the course of the project, the DCC performed two to three sites visits each year to monitor the ASU compliance with study protocol. Additionally, the distributed microcomputer data management system located at each ASU automatically tracked dates of interviewers and completeness of study forms and procedures. Notices were provided to the ASU immediately when protocol procedures were not followed. Each month, the DCC provided the steering committee, program office, and project coordinators with detailed reports indicating the status of every study participant and exceptions to the study protocol (missing procedures, visits outside recommended windows, etc.)

Data Quality Control

Data collection forms were subjected to extensive and immediate edits by the distributed data management system. Additionally, data underwent further edits at the DCC for cross-form consistency and repeated audits on specific values. During site visits, the DCC pulled study forms at random, compared values to electronic databases, and ensured that edit reports were documented and forms correctly updated.

Security

All study data were downloaded each night from the ASU distributed systems to the computers at the DCC. Every two weeks, the ASU performed an additional full backup of data files and sent diskettes to the DCC. All data bases were backed up at the DCC each night and copies of the data stored off-site in secure locations for disaster recovery.

DISCUSSION

The NCICAS project represents the largest epidemiologic research investigation ever conducted concerning the excess asthma morbidity among children in the inner cities. The data reported here describe the first phase of the NCICAS project, namely, the epidemiologic cross-sectional study of factors related to asthma among chil-
dren in the inner-city. The next step, the NCICAS Phase II intervention study, is currently underway and attempts to reduce asthma morbidity among these children. The NCICAS Phase I study focused on a very large sample (1,528 children and their caretakers); the extensive nature of the data collection via interviews, home visits, and assessments of both children and their caretakers provides a vast quantity of information about this population. A unique aspect of this project is the year-long follow-up of study participants to track asthma health care utilization and symptoms. Nonetheless, it is essential that these data be evaluated appropriately within the context of the study design and its recruitment and sampling procedures.

**Population Representativeness**

The NCICAS study is not an asthma prevalence study of children in the inner-city and was not intended to be a population-based sampling of inner-city asthmatics. Therefore, data presented for these children and their families must be considered within the context of the recruitment procedures. Although recruitment was spread across eight major urban areas and participants were recruited at both EDs and community clinics, a specific effort was made to recruit severely asthmatic children. The symptom and utilization data observed in this study is representative of the "severe" and "non-severe" recruitment strategies and the resulting population strata that such a recruitment scheme yields. Since this study employed an emphasis on both recruitment during an asthma attack and ED recruitment to enhance the more severe population, in the reports that follow all study data is presented by recruitment site and attack status when this distinction proved to be significant. However, as can be seen by the study-specific recruitment definitions and eligibility criteria, this recruitment scheme provides for a very wide range of asthmatic children living in the inner-city.

**Representativeness of Recruitment Sites**

NCICAS identified a group of recruitment sites serving a wide range of children in the inner-city. Because the various sites served different demographic subgroups, certain risk factors could potentially be confounded with recruitment sites. The degree of such confounding was controlled by establishing restrictions on the entry criteria for the various sites. For example, the community sites were primary care sites with a patient population living primarily in the study area and similar in demographic characteristics to the study area. Additionally, potential confounders were measured for adjustment during data analysis. Recruitment in non-medical sites such as schools, community centers, day care programs, churches, or job training centers might have allowed for identification of some families with the least access to medical care. However, in many of these non-medical sites, attendance is restricted to certain groups or is influenced by employment or similar factors, which could introduce other types of sample bias. Difficulties in identifying clear sampling frames would also have affected recruitment and the evaluation of non-participation. Non-medical sites were therefore not eligible for inclusion as recruitment sites.

**REFERENCES**

Palmes ED, Gunnison AF, Di Mattio J, Tomczyk C. Personal
Neas LM, Dockery DW, Ware JH, Spengler JD, Speizer FE, Fer-
Samet JM, Marbury MC, Spengler JD. Health effects and sources
Hasselblad V, Eddy DM, Kotchmar DJ. Synthesis of environmen-
Lowry T, Schulman LM. Silo fillers disease: A syndrome caused
Tovey ER, Chapman MD, Aalberse RC, Brown MJ, Platts-Mills TA. Mono-
Sporik R, Holgate ST, Platts-Mills TA, Cogswell JJ. Exposure to
Platts-Mills TA, Tovey ER, Mitchell EB, Moszoro H, Nock P,
Heyman PW, Chapman MD, Aalberse RC, Fox JW, Platts-Mills
Pollart SM, Mullins DE, Vailes LD, Hayden ML, Platts-Mills TA, Sutherland WM, Chapman MD. Identification, quantitation, and
Schou C, Lind D, Fernandez-Cal das E, Lockey RF, Lowenstein H. Identification and purification of an important cross-reactive al-
Platts-Mills TA, Tovey ER, Mitchell EB, Moszoro H, Nock P, Wilkins S. Reduction of bronchial hyperreactivity during pro-
Lind P, Hansen OC, Horn N. The binding of mouse hybridoma and human IgE antibodies to the major fecal allergen, Der p I, of
Tovey ER, Chapman MD, Wells CW, Platts-Mills TA. The dist-
Hasselblad V, Eddy DM, Kotchmar DJ. Synthesis of environmen-
Samet JM, Marbury MC, Spengler JD. Health effects and sources of indoor air pollution. Part I. Am Rev Respir Dis. 1987; 136:
Neas LM, Dockery DW, Ware JH, Spengler JD, Speizer FE, Ferr-
Neas LM, Dockery DW, Ware JH, Spengler JD, Speizer FE, Ferr-
Data Coordinating Center
The DCC provided epidemiological, statistical, research, and administrative support for the multicenter project. The coordinating center organized training, meetings, conference calls, and prepared and distributed study protocols and materials.
Committee Structure

During the course of the study development, implementation, and analysis, a variety of committees, subcommittees, and working groups were formed. The following committees were central to the planning and implementation of the project:

Steering Committee—The Steering Committee (SC) served as the principal decision-making body of NCICAS. The SC was composed of the principal investigators from each of the eight ASUs, one representative from the Program Office, and the principal investigator of the DCC. The SC provided oversight for the work of the various scientific and administrative subcommittees below.

Adherence Committee—developed the measures of adherence for the baseline interview and methods of facilitating medicine identification and use.

Cultural Committee—reviewed all study materials and forms to ensure that these items were culturally appropriate. This committee reviewed closely the results of pilot testing and provided feedback for form and question modification to improve the study participants’ understanding and the appropriateness of questions. Guidance in determining literacy levels and assessments was also provided by this committee.

Economic Impact Committee—provided questions and instruments to assess the economic impact (both direct and indirect) of the NCICAS population’s asthma. Additional funds were provided by Glaxo Pharmaceutical Corporation to facilitate the economic data collection.

Environmental Factors Committee—established protocols for interviews regarding home environment, home visits, dust collection and analysis, and NO2 measurement.

Health Care Delivery Committee—designed and piloted assessment of study participants’ access to the health care system and their utilization of health care.

Host Intrinsic Committee—defined measures of medical and birth history for family, caretaker, and child.

Outcome Measures Committee—developed measures of morbidity and utilization for baseline assessments and year-long interval telephone assessment.

Population/Recruitment Committee—designed population recruitment protocol, oversaw selection of recruitment sites, and geographic determination of inner-city boundaries. This committee also monitored recruitment throughout the 9-month recruitment period and adjudicated recruitment and eligibility questions.

Protocol Development Committee—prepared the study protocol utilizing the input of the various working committees.

Psychosocial Committee—selected, piloted, and developed appropriate measures of psychosocial factors which were anticipated to play a role in asthma morbidity.

Administrative Committees

The following committees were administrative in nature and provided support to the steering committee for on-going administrative issues.

Ethics Committee—provided guidance and oversight of ASUs consent forms, as well as overall study procedures.

Publications Committee—served as the administrative committee for identifying areas for manuscript and abstract development, established writing groups, and provided review of these documents.

Publicity Committee—reviewed and approved public statements regarding the NCICAS project for both local and national release.

APPENDIX B

The National Cooperative Inner-City Asthma Study, Phase I, was a collaboration of the following institutions and investigators. Principal investigators are indicated by asterisks.