

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY III

**Training Manual
for
Allergy Component**

Westat, Inc.
1650 Research Boulevard
Rockville, MD 20850
(301) 251-1500

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1. INTRODUCTION

1.1 Overview of the Allergy Component

The allergy skin testing component of NHANES III has been developed by NCHS in collaboration with the Center for Biologics Evaluation and Research, Food and Drug Administration (CBER, FDA). This survey will help NCHS and CBER, FDA measure the prevalence of allergies in the United States and determine if the prevalence has changed since previous HANES surveys, which indicated that approximately 20 percent of the U.S. population is affected by allergic diseases. The Health Resources and Services Administration will use the data to measure the degree to which allergies in the population impact on health care delivery systems. The FDA will use the data on standardized allergens to assess their reactivity in the general population. The National Heart, Lung, and Blood Institute will use the allergy data in conjunction with other exam and interview data to increase our understanding of chronic obstructive lung disease.

Data on allergies will be collected during interviews and examinations of SPs. During the interview, data will be collected on four main types of allergies: asthma, hayfever, eczema, and food and drug allergies. In addition, the questions will be designed to obtain information on trigger factors, severity, medication use, and hospitalizations. The examination component will consist of the application of 12 skin tests by the prick-puncture technique, and collection of blood for measurement of serum IgE (immunoglobulin) levels.

1.2 General Overview of Procedures

Allergens are extracts of certain foods, animal insects, pollen, or molds which are used to test a person for hypersensitivity to specific substances. The allergen skin tests administered in NHANES III are designed to minimize constitutional reactions necessitating the use of emergency medical procedures. Using the prick-puncture technique during each stand, approximately 134 SPs aged

6-59 will be tested for the following allergens and controls:

- | | |
|---|---|
| 1 - Negative Control (glycerinated diluent) | 7 - Peanut |
| 2 - White oak | 8 - Russian thistle |
| 3 - Cat | 9 - German cockroach |
| 4 - Mite | 10 - Bermuda grass |
| 5 - Alternaria | 11 - Ragweed |
| 6 - Rye grass | 12 - Positive control
(histamine base) |

2. EQUIPMENT

2.1 Description of Exam Room in MEC

The allergy component takes place in the Body Measurement Room in the MEC. The technician and SP sit on either side of a table on which the SP's arm rests during the administration of the allergy tests and reading of the reactions.

2.2 Description of Equipment and Supplies

2.2.1 Inventory of Supplies and Equipment

The following is a list of the supplies used in the allergy component:

- Cold box to store allergen vials during exam sessions
- Rack to hold allergen vials
- Timer with buzzer
- Lamp (with 75-watt incandescent bulb)
- Magnifying glass
- Clear plastic template to mark test sites (large, medium & small sizes)
- Metric ruler (plastic, transparent, flexible)
- Needle disposal box (biohazard container)
- Syringes to transfer solutions (1cc with 20 gauge needles 3/4" or 1/2")
- Black marking pen (fine, rolling writer, washable ink)
- Needles (BD 25 gauge, 5/8 inch)
- Alcohol sponge wipes
- Gloves
- Vials of allergen extracts
- Gauze pads 4x4's

2.3 Equipment and Supply Setup Procedures

2.3.1 Start of Stand Procedures

Fresh solutions are used at the beginning of each stand. Check to make sure there is an adequate supply of all 12 extracts for the anticipated number of SPs to be tested for allergy during the stand.

At the start of each stand, the freeze-dried extracts (cat hair, rye grass, russian thistle, short ragweed) must be reconstituted with diluent. To reconstitute each extract, you will need five (5) 1 ml. vials of the freeze-dried extracts; four (4) 5 ml. syringes; four (4) 20 gauge needles, 1" in length; and a 5 ml. dropper vial filled with diluent.

Using an alcohol prep, wipe the tops of the 1 ml. vials containing the freeze-dried extract. Put a 20 gauge needle on the syringe. Draw up 5 ml. of diluent from the 5 ml. dropper vial. Inject 1 ml. of diluent into each vial. Shake well. When all the material has dissolved, withdraw the 1 ml. of reconstituted extract in each vial using the same syringe you used for injection into that vial. Finally, inject all 5 ml. of reconstituted extract into the 5 ml. dropper vial from which you originally withdrew the diluent. Label the dropper vial with the appropriate name and number.

Treat the reconstituted solution as you would the other extracts. Repeat this procedure for each set of freeze-dried extracts.

2.3.2 Calibration Procedures

There is no equipment to be calibrated.

2.3.3 Daily Procedures

At the beginning of each session, remove the tray of vials from the refrigerator and place it in the exam room.

At the end of the session, before refrigerating the tray of vials, make sure there is enough of each

solution to conduct allergy testing during the next session. Place the top of the cold box in the freezer.

2.4 Care and Maintenance of Equipment and Supplies

To maintain the stability of the test allergens throughout a stand, allergen vials should be kept in the refrigerator when not in use; and in the cold box in the exam room when allergy testing is taking place.

You should handle the allergen solutions with care, however they are not biohazardous. Thus, if an allergen solution spills on someone or on the floor or other object, merely wipe it with a damp cloth and throw it away.

2.5 End of Stand Procedures

2.5.1 Equipment Breakdown

(There is no equipment to be broken down.)

2.5.2 Packing Supplies and Equipment

Discard all **open** vials of allergens. Any **unopened** vials should be mailed back to Westat, on ice, via next day delivery.

3. EXAMINATION PROTOCOL

3.1 Eligibility Criteria

3.1.1 Sampling Procedures

You will not need to conduct the sampling of appropriate SPs for allergy testing, but you should be aware of the procedure used.

The sampling procedure to determine which examinees receive allergy testing (and which receive CNS) is as follows:

<u>Component</u>	<u>SP Age</u>	<u>Sample</u>
Allergy	6-19 years	All
	20-59 years	1/2 sample - even examinee number
(CNS)	20-59	1/2 sample - odd examinee number

The final digit of the Serial Number, not the check digit, should be used to determine the odd/even designation.

3.1.2 Medical Exclusion

SPs with certain medical conditions will not be allowed to have the allergy skin tests. To determine which SPs are not eligible, the health technician should ask the questions as they appear on the screen or hard copy form (Exhibit 3-1).

Question 1: "Are you now having problems breathing?" If the SP answers "No", you skip questions 2 and 3 which ask for additional information on breathing problems, and go on to question 4. If the SP answers "Yes", you continue on to question 2 for further questioning on breathing problems.

ALLERGY TEST

AGES 6-19 ALL AND 20-59 EVEN

STAFF NO. _____

SAMPLE NO. _____

1. Are you now having problems breathing? 1 Yes (Q2) 2 No (Q4)
2. Do you usually have breathing problems? 1 Yes (Q3) 2 No - Exclude
3. Is your current breathing problem worse than usual? 1 Yes - Exclude 2 No (Q4)
4. Have you had a past severe reaction to allergen skin testing? 1 Yes - Exclude 2 No
5. Does sample person have severe eczema or infection on both arms? 1 Yes - Exclude 2 No

IF ONLY ONE ARM USED, INDICATE WHICH ARM: right left (Indicate reason below for use of one arm.)

	Flare		Confluent		Wheat		**Minutes	*Reason for no injection of this Allergen
	Length (mm)	Width (mm)	Yes	No	Length (mm)	Width (mm)		
1. Negative Control	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
2. White Oak	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
3. Cat	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
4. Mite	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
5. Alternaria	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
6. Rye Grass	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
7. Peanut	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
8. Russian Thistle	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
9. German Cockroach	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
10. Bermuda Grass	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
11. Ragweed	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
12. Positive Control	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____

- *Reason no injection for specific allergen:
- 4 No allergen or supplies
 - 7 Refused due to reported allergy
 - 9 Refused - other reason

**Minutes from administration to reading (only if differs from 15 minutes \pm 5 minutes).

Question 2: "Do you usually have breathing problems?" If the SP answers "No", he/she is excluded from the allergy component, and you do not ask any additional questions. However, if the SP answers "Yes", you continue on to question 3.

Question 3: "Is your current breathing problem worse than usual?" If the SP answers "Yes", the SP is excluded from the allergy component, and no further questions are asked. If the SP answers "No", continue on to question 4.

Question 4: "Have you had a past severe reaction to allergen skin testing?" If the SP answers "Yes", the SP is excluded from the allergy component, and no further questions are asked. If the SP answers "No", continue on to question 5.

Question 5: "Does sample person have severe eczema or infection on both arms?" If you observe this, record "Yes". The SP is excluded from the allergy component, and no further questions are asked. If you do not observe this, record "No". You have completed the Medical Exclusion portion of the component, and administer the allergy skin testing to this SP.

3.2 Pre-Examination Procedures

Make sure all the supplies you need are arranged so they are easily accessible to you.

3.3 Examination Procedures

3.3.1 Protocol Procedures

Administration of the Allergen Skin Tests

1. Briefly describe the allergen skin test procedures to the SP. Use your own words to explain that you will clean the arm; mark the skin test sites with a washable marker; apply 12 drops of allergen solution; gently prick the skin; wipe off the solution; wait 15 minutes; measure the reactions. In describing the procedure, use the word "scratch", not "puncture", and reassure the SP this is not painful. For an SP who is especially nervous, one suggested technique is to scratch the back of his/her hand with a needle to show how painless it is. Explain that almost everyone will develop a positive reaction to the control (histamine) solution.
2. While explaining the procedures to the SP, put on your gloves. These should be worn throughout the application portion of the allergy testing. For each SP you should put on a new pair of gloves.

3. Ask the SP to clean the inside of both forearms with alcohol sponge wipes and let air-dry. If the SP has eczema or a skin infection on one arm, s/he should clean the forearm and upper arm of the unaffected arm.
4. Select the appropriate template for each SP, reserving the smaller version for small adults or children. Using the template as a guide (see attached diagram, Exhibit 3-2, of the allergen positions on the template), serially number the 12 skin test sites.

For most SPs, both forearms will be used for the allergen skin testing. With the SP's palm facing up, place the template on the **left forearm** at the wrist, and place a dot to indicate the position of each of the 6 test sites (Sites 1-6). Then move the template to the **right forearm** and repeat the procedure for test sites 7-12. (See Exhibit 3-3).

In the rare case when only one arm is available (e.g., if the SP has a skin infection on one arm), place the template on the forearm and upper arm of the unaffected arm. Then mark the sites as with both forearms. (See Exhibit 3-4).

You will note that the template is designed to help you avoid the vascular areas near the elbows and wrists (one inch above the wrist, and one inch above and one inch below the elbow crease).

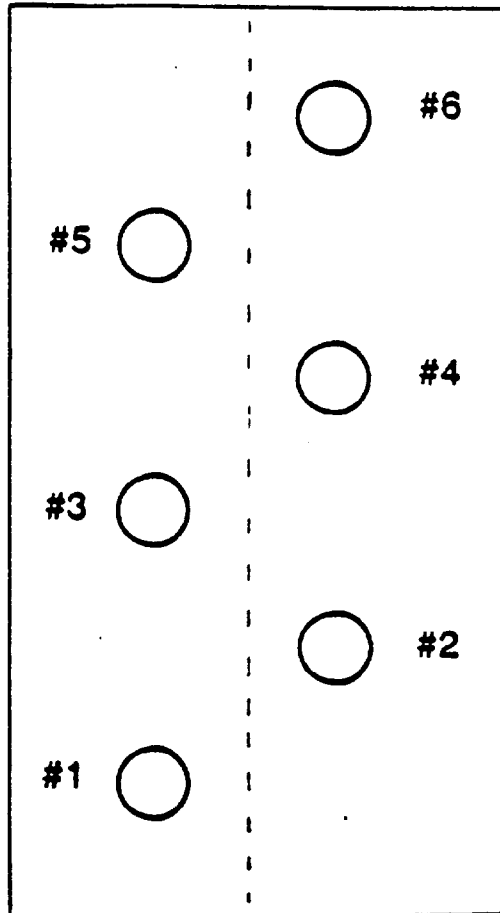
After you have placed the 12 dots on the arms, number them serially as indicated in the schematic diagram. For all the procedures described below, it is essential to always do them in this numerical order.

5. Put a drop of each of the first 3 allergen solutions next to the respective numbers. Use small drops of allergen solutions to prevent them from running together. Try not to touch the skin with the dropper tip.

If the dot happens to be on a blood vessel (vein or artery), place the drop off to the side, away from the vessel. **DO NOT PUNCTURE A BLOOD VESSEL.**

6. Beginning with the first test site, insert the needle tip, bevel up, at a 30-45 degree angle to the skin, into the allergen drop to wet the needle tip. (See Exhibit 3-5.) Then, insert the needle tip into the skin deep enough to cover the bevel. Lift the needle tip to tent the skin and to create a needle track for the solution to flow into (see Exhibit 3-6). Maintain the tent for a few seconds. Remove the needle tip and dispose of the used needle in the needle box.
7. As soon as you have made the first prick, set the timer for 15 minutes.
8. **USE A SEPARATE NEEDLE FOR EACH SOLUTION.** Prick sites 2 and 3 as described above. Use a dry gauze to wipe off each of the drops, being careful not to intermingle the allergen solutions. Then place the drops on sites 4-6, prick those, and wipe them. Repeat the procedure for sites 7-9, and 10-12.

Exhibit 3-2. Schematic diagram of allergen positions



Repeat for sites 7-12

Exhibit 3-3. Numbering the test sites (2 arms)

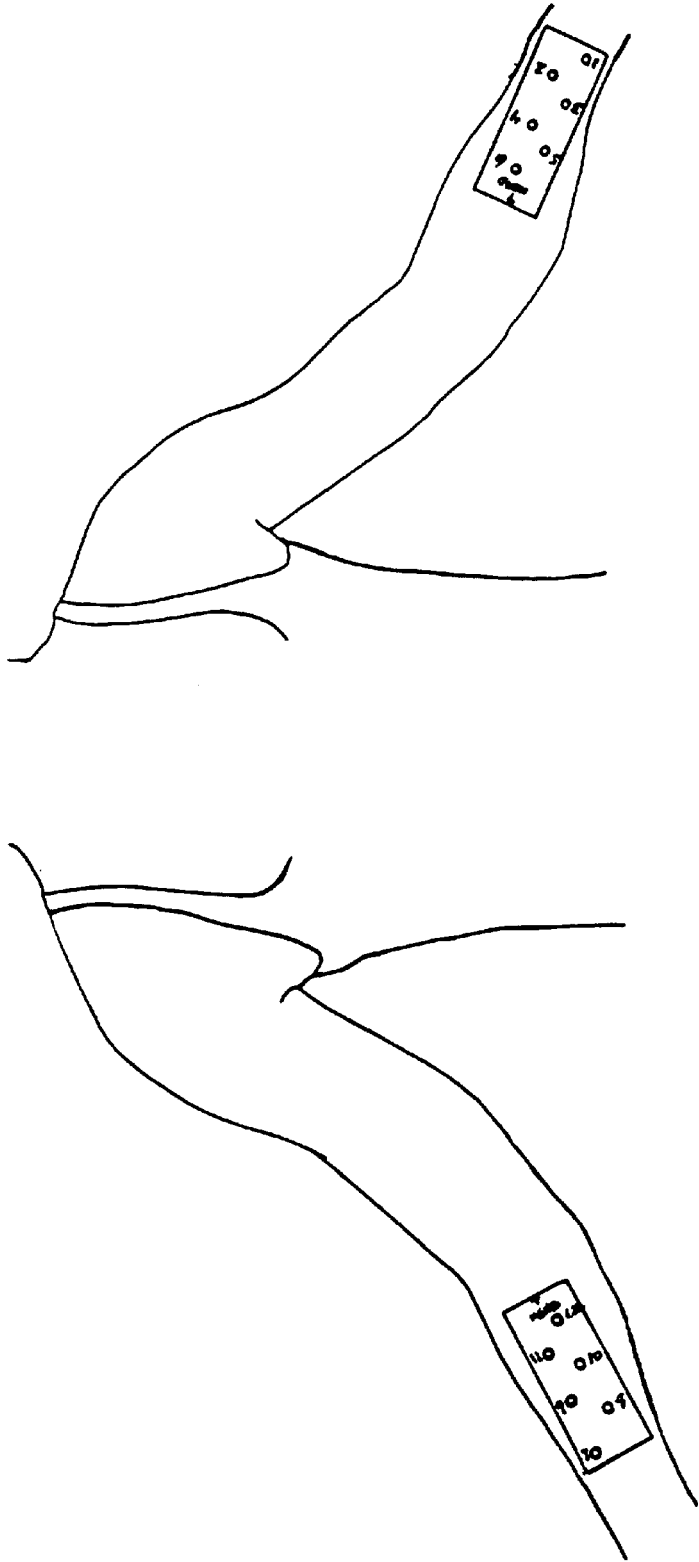


Exhibit 3-4. Numbering the test sites (1 arm)

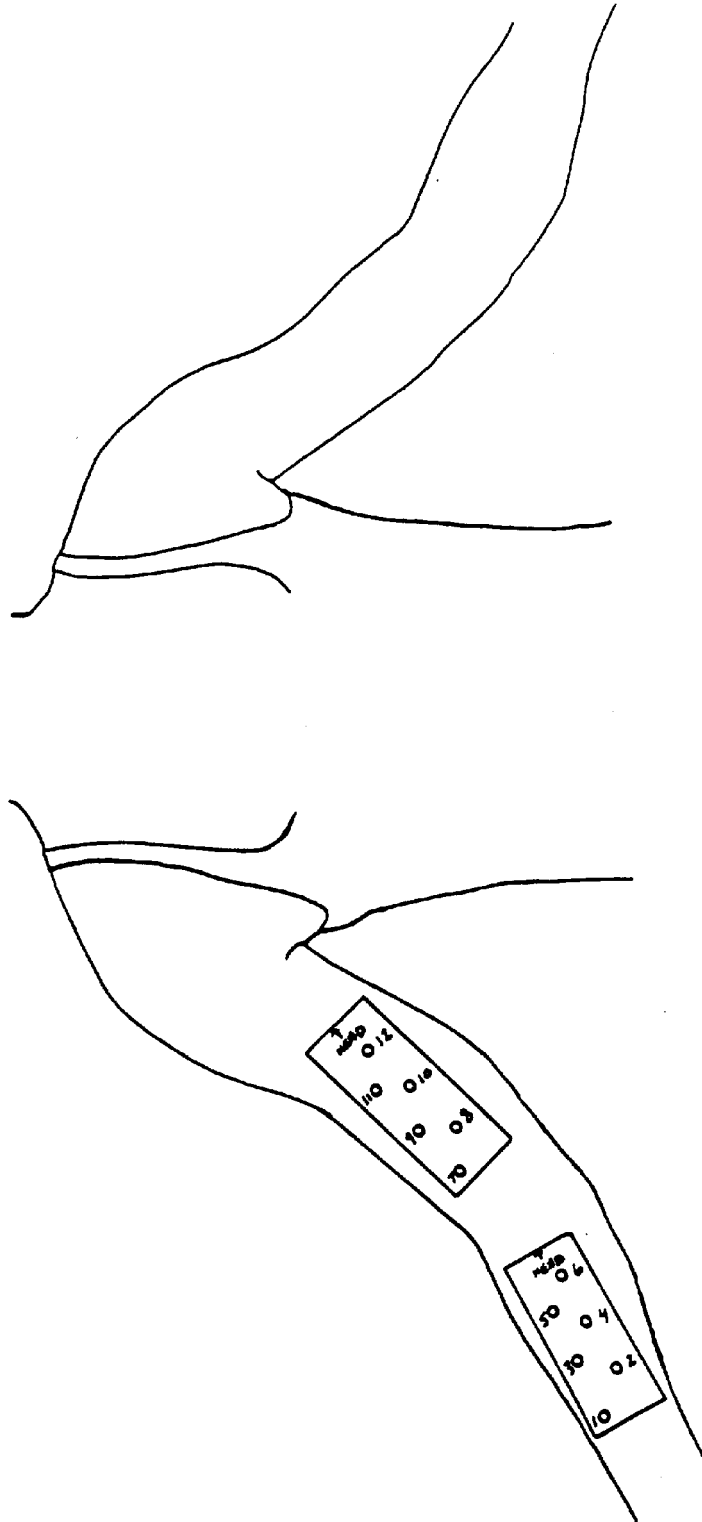
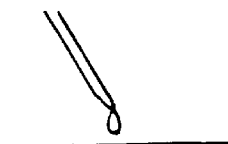


Exhibit 3-5. Inserting the needle

1



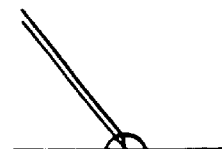
Apply a 5 mm drop of allergen solution without touching the dropper tip to the skin.

2



Position the needle tip, bevel up, at a 30°-45° angle to the skin surface.

3



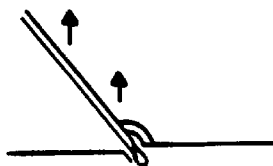
Begin needle insertion by wetting the needle tip and bevel in the allergen drop.

4



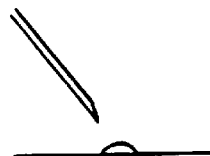
Continue inserting the needle, piercing the drop and the skin simultaneously, until the bevel is covered under the skin.

5



Lift the needle tip 3-5 mm to tent the skin and to create a needle track for the solution to flow into. Maintain tent for a few seconds.

6



Remove the needle tip.

Exhibit 3-6. Testing the skin



Correct Tent



Incorrect Tent

9. Instruct the SP not to scratch his/her arms until the skin tests have been read.

NOTE: During the waiting time, the SP will receive the body measurement testing.

10. When the timer goes off, record the results according to the instructions in the next section.

Reading the Reactions

Reactions which meet certain size criteria will be measured and recorded. A wheal is a smooth, slightly elevated area which is redder or paler than the surrounding skin; it may change its size and shape, it disappears quickly or within a few hours. A flare is the red outermost zone of a wheal reaction.

If a skin test reaction has at least one diameter (width or length of wheal or flare) which is 3 mm or greater, measure and record all 4 measurements (length and width of flare, and length and width of wheal), even if some of the other measurements are less than 3 mm or non-existent. However, if all 4 diameters of a skin test reaction are less than 3 mm, record zeros for all the measurements. Follow the steps described below.

1. When the time goes off, 15 minutes after the first prick, begin outlining the reactions. This should be done as close to 15 minutes as possible ± 2 minutes. In the case of an extreme reaction, safety precautions, or some other reason, measurements of responses may have to be done at a time other than the standard time after the prick. If there is more than a 5 minute deviation from the usual 15 minutes, (i.e., if the reaction is read after less than 10 minutes or greater than 20 minutes), record the time of the reading and record the reason.
2. Use a marking pen and gentle pressure to outline the flares and wheals of appropriately-sized reactions. It is important to outline the erythema (flare) and wheal in their entirety prior to measurement. In marking the erythema, be careful to outline only the distinctly pink areas observed, and not to include normally pigmented skin in addition to the reaction. (Note: As an internal check on accuracy of outlining, observe the outlined sites after cleaning the arm with alcohol at the end of the procedure. Usually, the erythema becomes more distinct after the alcohol cleansing while the penned outline is still visible. If there is a large discrepancy between the area of the penned erythema and the penned outline, use this immediate feedback to be more conservative in outlining responses in the future.)

If there is any difficulty in defining the borders of the wheal and flare reactions, especially in dark-skinned individuals, use oblique lighting to enhance discrimination of the boundaries. Use a bright lamp with a 75-watt incandescent bulb or fluorescent light. Bright sunlight is also helpful. Do NOT wipe the reaction with alcohol.

Once the outlines are drawn, do not retrace them on the SP's skin. Do not make any marks on the SP's skin for those skin tests for which there was no reaction or for which the reaction was very small.

3. For approximately-sized reactions, measure the length and width of each flare and wheal from the inner edge of the penned outline. Although the flare and the wheal tend to be concentric "circles", when taking the measurements you should consider the flare and wheal as separate entities. (See Exhibit 3-7.) First, measure the length and width of the flare; and then independently measure the wheal. To do this, you will use a plastic, transparent, flexible mm ruler. The length is defined as the largest diameter, and the width is defined as the diameter perpendicular to the length at its midpoint. On rare occasion, for a perfectly circular reaction, the length and width will be equal.
4. Enter the results into the computer or onto the hard-copy recording form as described below.

3.3.2 Examination Form

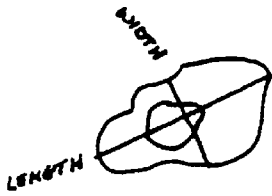
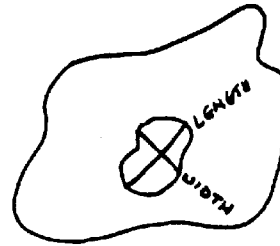
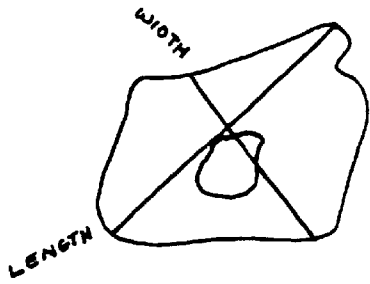
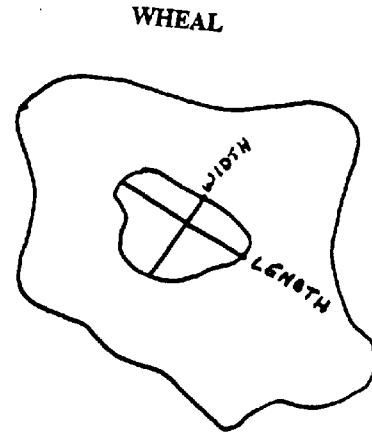
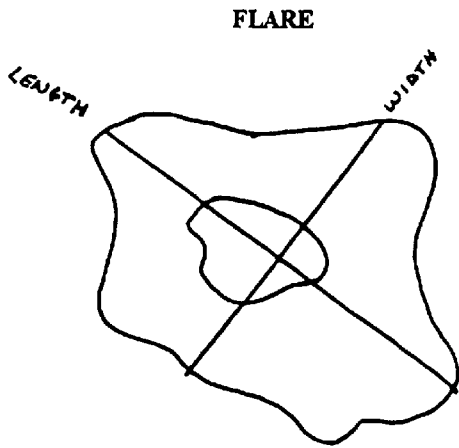
As you record the results of the allergen skin tests, the computer screen will look like the hard-copy form (Exhibit 3-8). You will note that the top part of the form is the safety screen in which individual SPs are excluded from this testing. This information should be recorded as follows:

- **Staff No.** - Record the number of the person administering the allergen skin tests.
- **Sample No.** - Record the sample person's Sample Number.

Criteria for medical exclusion are described in Section 3.1.2 of the manual. The reasons the examinee is excluded from allergy testing should be recorded as follows:

- Q3 **Breathing problems at exam time** - If the SP says he/she is having trouble (out of the ordinary) breathing in his/her chest, the SP is not eligible for the allergy skin tests, and this box should be checked.

Exhibit 3-7. Measuring flare and wheal reactions



ALLERGY TEST

AGES 6-19 ALL AND 20-59 EVEN

STAFF NO. _____

SAMPLE NO. _____

1. Are you now having problems breathing? 1 Yes (Q2) 2 No (Q4)
2. Do you usually have breathing problems? 1 Yes (Q3) 2 No - Exclude
3. Is your current breathing problem worse than usual? 1 Yes - Exclude 2 No (Q4)
4. Have you had a past severe reaction to allergen skin testing? 1 Yes - Exclude 2 No
5. Does sample person have severe eczema or infection on both arms? 1 Yes - Exclude 2 No

IF ONLY ONE ARM USED, INDICATE WHICH ARM: right left (Indicate reason below for use of one arm.)

	Flare		Confluent		Wheal		**Minutes	*Reason for no injection of this Allergen
	Length (mm)	Width (mm)	Yes	No	Length (mm)	Width (mm)		
1. Negative Control	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
2. White Oak	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
3. Cat	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
4. Mite	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
5. Alternaria	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
6. Rye Grass	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
7. Peanut	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
8. Russian Thistle	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
9. German Cockroach	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
10. Bermuda Grass	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
11. Ragweed	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____
12. Positive Control	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____	_____	_____

*Reason no injection for specific allergen:

- 4 No allergen or supplies
- 7 Refused due to reported allergy
- 9 Refused - other reason

**Minutes from administration to reading (only if differs from 15 minutes \pm 5 minutes).

Exhibit 3-8 (continued)

RESULTS OF EXAMINATION:	
1	<input type="checkbox"/> Test done
2	<input type="checkbox"/> Test incomplete
3	<input type="checkbox"/> Test not done
REASONS TEST INCOMPLETE OR NOT DONE:	
1	<input type="checkbox"/> No allergen or other supplies
2	<input type="checkbox"/> Insufficient time available or room not available
3	<input type="checkbox"/> Examinee refused or uncooperative
4	<input type="checkbox"/> Examinee medically excluded by staff for safety
5	Comments: _____

Q4 **Past severe reaction to allergen skin testing** - This should be determined by asking the SP about his/her previous experiences.

Q5 **Severe eczema or infection, both arms** - If this is observed just before the exam, check this box. (Remember that if this condition exists on only one arm, the tests should be administered on the unaffected arm.)

In most cases, the allergy skin testing will be administered on both arms, and this does not need to be indicated on the form. However, in the unusual case when only one arm is used, it is important to specify on the form whether it was the **right arm** or **left arm**.

The size of the reactions should be completed as follows:

- **Flare** - Record the length and width of the flare for each reaction in the appropriate columns.
- **Confluent** - Indicate if the reactions to the solutions were confluent (ran together).
- **Wheal** - Record the length and width of the wheal for each reaction in the respective columns.
- **Minutes** - The reactions will almost always be read 15 minutes after the prick. Do not record the actual number of minutes unless the time was less than 10 minutes or more than 20 minutes.
- **Reason for no injection of this allergen** - In the rare case that a specific allergen solution was not injected, record this in the appropriate column, indicating the reason:

Code 4 **No allergens or supplies** - If, for some reason, supplies are unavailable, check this box.

Code 7 **Refused due to reported allergy** - If the SP refuses to be tested for a specific allergen for this reason, check this box.

Code 9 **Refused - Other Reason** - If the examinee is excluded from allergy testing for a reason other than those described above, check this box.

3.4 Postexamination Procedures

1. Ask the SP to clean his/her arms with an alcohol wipe.

2. Do not let the SP leave the MEC until at least 30 minutes have passed since administration of the allergen skin tests. If the SP insists on leaving, inform the MEC physician.
3. Record time out on Allergy Daily Log.

4. LOGS AND RECORDS

4.1 Daily Log

4.1.1 Automated System

The automated version for the allergy testing component is designed to duplicate the hard copy form. The information in Appendix A includes a series of memos from the programming branch at the National Center for Health Statistics that describe the procedure for operating the automated system.

Examples of the program display screens are also included in Appendix A.

4.1.2 Hard Copy Daily Log

Attached is a copy of the hard copy daily log for the allergy component (Exhibit 4-1). At the top of the form, the first technician to perform allergy testing during a session should enter the date, exam session, stand number and location. As allergy testing is going on throughout the day, each technician should enter the appropriate information for each SP tested. Line A should be used to record the set up time, i.e., the time it takes to prepare for and apply the allergen solutions. Line B is used to record the reading time, i.e., the time it takes to circle, measure, and record the reactions. Do **not** include the waiting time.

4.2 Calibration Logs

There are no calibration logs for the allergy component.

4.3 Shipment of Forms and Logs

Use the standard MEC procedures for shipping forms and logs.

**NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY III
ALLERGY LOG**

Date: ___/___/___
 Exam Session: I II
 Morn. Aft. Eve.

Stand Number _____
 Location _____

SP ID #	Time In / Time Out	Completed		If no, reason/ other comments	Examiner ID #
		Yes	No		
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____
	A ___:___/___:___ B ___:___/___:___	<input type="checkbox"/>	<input type="checkbox"/>		_____ _____

5. QUALITY CONTROL

Quality control will be performed in several ways. Periodic visits to the field will be made by Westat and NCHS staff along with expert consultants to observe how the skin testing technique is being performed. The actual data itself will be monitored for size and frequency of reaction to the various allergens. The only replicates which will be performed for the allergy component are the "100% replicates," who will receive allergy skin testing.

6. SAFETY PROCEDURES

6.1 Equipment and Supply Precautions

Standard procedures regarding the use of needles and gloves should be practiced.

You should handle the allergen solutions with care, however, they are not biohazardous. Thus, if an allergen solution spills on someone or on the floor or other object, merely wipe it with a damp cloth and throw it away.

6.2 SP Movement and Positioning

During the allergy testing component, the SP should always be seated, and his/her arm should rest on a hard surface (table).

6.3 Emergency Procedures

Generalized reactions to the allergen skin tests are not expected; however, if one does occur it may be sudden and sometimes serious. It is important that the examinee immediately receive the proper emergency treatment while awaiting transport to the hospital. **Do not wait** for the full development of an adverse reaction; if there is any question whether or not a reaction is occurring, notify the physician immediately. The physician has the responsibility of diagnosing and treating any adverse reactions to allergen skin testing.

Signs of an adverse reaction can take many forms. The examinee may complain of throat or chest tightness, generalized itching (other than at the site of the allergen skin test), nasal congestion, or trouble breathing. Other signs of an adverse reaction include sneezing, coughing or feeling "funny", faint, dizzy, or weak, or sore throat. If the examinee has a cough or a cold before receiving the allergen skin tests, an adverse reaction may present by an increase in the frequency or severity of the pre-existing cough. Continuation of a preexisting cough or the sniffles at the same level after skin testing is **not** a sign of an adverse reaction. Development of any new symptoms regardless of severity not present prior to testing requires notification of the physician.

If the SP sneezes or coughs or says she/he feels funny, faint, dizzy, or weak, treat for vasovagal reaction (ease the examinee to a lying position, and elevate his/her feet, and notify the physician).

After the physician arrives, fully describe the symptoms the examinee is experiencing. The physician will evaluate the examinee and determine whether or not an adverse reaction is occurring. If an adverse reaction, which requires any drug therapy, is determined to have occurred, the examinee must be transported to the nearest hospital emergency room by an ambulance. The physician will provide basic stabilization treatment while awaiting the arrival of the ambulance.

Appendix A

User Documentation for Allergen Skin Test Screens

September 9, 1988

User Document for Allergen Skin Test V1.01

The Allergen Skin Test Automation System is made up of these screens: the introduction screen, the 5 questions screen, the injection screen, the readings screen, and the results screens. The examinee's name and sample number are displayed at the top of each screen. The keys and their functions are described below.

Keys:

The F18 key displays the current version number of the automation for this application at the bottom of the screen.

The F9 key prints the current screen.

The <Return> key moves the cursor to the next data entry field on the same screen. On the question screens, this key advances to the next screen.

The <up arrow> and <down arrow> keys move the cursor up and down columns. "Up" won't cause movement on the injection and readings screen if the cursor is already at the first line, and "down" won't cause movement if the cursor is at the last line. On the question screens, the arrow keys are not needed.

On the injections screen, "up" goes to the arm field of the previous line, and "down" goes to the arm field on the next line. On the readings screen, these keys move the cursor to the previous or next lines, remaining in the same column.

The <Prev Field> key (F12) moves the cursor to the previous field. On the injection screen, the cursor will not move if already placed on the arm field. On the readings screen it will remove data in the field it is leaving if a bad code has been entered.

The <Next> (Next Screen) key is used to move to the next screen. For the exclusions and readings screens, messages will appear if the screen contains incorrect data, and the cursor will not leave that screen until errors have been entered.

The <Prev> (Previous Screen) key is used to move back to the previous screen. From the Injection screen it returns to the first question.

The <Select> key puts an "X" in the field in which the cursor is positioned. It is used only on the introductory screen to select the proper exam component, and on the results screens to select options for exam completion.

The <Insert Here> key is used only on the readings screen, and allows the technician to enter row lengths and widths of "0" and Confluent code "N" with a single key stroke when the cursor is positioned at the "Flare Length, or to enter a lapse time of "015" minutes with one key stroke when the cursor is positioned at the Lapse Time field.

The <Remove> key is used on the readings screen to wipe out data entered by the Insert key. At the Flare Length, this key will blank out the lengths and widths and confluence codes for that line; at the Lapse Time it will blank out that field. When the cursor is positioned on fields other than Flare Length and Lapse Time, the Remove key will blank out the Not Read code in that line. These features are useful in correcting wrong key strokes.

The <PF4> key is used to abort data entry and move to the results screen. It will be most useful when an exam is interrupted to get to the results screen before usual data entry has been completed. In the current version this key will not leave the injections screen unless all data have been properly entered; it will leave the readings screen if null values are present. The PF4 key is not needed on the injections screen since the next screen is the results screen anyway.

The <space bar> is used to clear out erroneous data in a field. On the readings screen the F19 key can be used to clear the current field with one key-stroke.

The <Next>, <Prev>, and <PF4> keys usually need to be pressed twice before their action is fully taken. The first press will display a message at the bottom of the screen that requires acknowledgment. The second press acknowledges the message and brings up the next, previous, or result screen as appropriate.

The message "No function defined for this key" appears when a key has been pressed that is not among the above list. Just press the desired key to continue.

Screens:

The first screen displayed is the introductory screen, and the last is the results screen. These screens are the same in all MEC applications and are documented separately.

After selecting "Allergy Injections" on the introductory screen, the question screens will be displayed. All questions must be answered by the codes displayed. Skip patterns are automatic. For some answers the examinee is excluded from testing and the next screen to be displayed will be the exit screen. If the examinee is not excluded, the next screen will be the injections screen, and the test may proceed.

If the usual injection protocol is being used (first 6 injections on the left arm, last 6 on the right), and all allergens are injected, no entry is needed on this screen. If the injection protocol does not follow the usual pattern, and/or if one or more allergens are not injected, the codes for "arm" and/or "no injection" should be corrected for the appropriate allergens. Data on this screen will be recorded as shown after any changes. Appropriate codes for the arm field are "2" or "L" for left and "1" or "R" for right. Codes for allergens not injected are shown on the screen. The names and sequence numbers of allergens cannot and must not be updated.

The readings screen will appear after selecting "Allergy Readings" from the introductory screen. When it comes up, if the message "Query caused no records to be retrieved" appears and the allergen sequence number field is blank, do not attempt to proceed; press the Prev key to return to the introductory screen. The message means that exclusion and injection data for this person have not gone into the data base, and that the "Allergy Injections" choice should have been made instead of "Allergy Readings."

The readings screen requires the most keying by the technician. Certain program features have been included to reduce key strokes.

Lengths and widths: entries can be 0 to 120. If a reaction is 3 mm, enter the "3"; the field will be padded to the left with blanks when the <Return> key is pressed. If a reaction is 15 mm, enter "15" and one blank will be padded to the left. If a reaction is 101 mm, all three digits must be entered. A width cannot be greater than a length. If 0 is entered for a length, the corresponding width of zero will appear and need not be entered. A width greater than a length will cause the cursor to move back to the length field in case it is the one needing correction. If it is not, press the <Return> key to move to the width and correct all three digits. Once padding has been done corrections on padded fields require that all three digits be updated. A length or width that cannot be determined can be entered as "888" but all three eights must be keyed. Otherwise padding will take effect and the field will look like an entry of "008". If the examinee refused to allow a reading to be done or if it is not done for some other reason, press the <Return> key when the cursor is positioned at the flare length field without entering a number; this will cause the cursor to move to the Not Read field where a code can be entered. The Not Read Field is usually skipped in normal data entry, and this is the best way to get to it. If data are entered and later found to be on an allergen not read, blank out the flare length and press <Return> to go to the Not Read code; after its entry, pressing <Return> will clear out the previous data. If Not Read is entered and later found to be keyed on the wrong allergen, it should be cleared by the space bar or F19 or Remove before reading data are entered. Entering values in the Flare Length will also clear out the Not Read field, since readings and Not Read are inconsistent for the same allergen. (Not true if the Insert key is used to enter values at the Flare Length in the current system.)

Often there is no reaction to most allergens. When the cursor is placed at the flare length, press the <Insert Here> key to get zeros in both lengths and widths, "N" in confluent, and move the cursor to the lapse time field.

Confluent field: entries should be "1" or "Y" (yes), or "2" or "N" (no). If it is not possible to decide, codes "8" or "U" (unknown) can be used. If the wheal and flare lengths are all zero, the confluent code will be made "2" for "No" regardless of what confluence code was entered. If the wheal and flare widths are all "888", the confluent code will be made "8" regardless of what was entered.

Lapse time: entries should be 10-20 minutes. The field is three digits and will be left-padded with zeros if one or two digits are entered. If the elapsed time between injections and readings is 15 minutes as targeted, the keyer can press the <Insert Here> key when the cursor is positioned at the lapse time field and the value "015" will be put into the lapse time with one key stroke. The lapse time field must be entered in the automated system.

The arm code for each allergen is expected to be correctly entered on the injection screen when injections are done. If a mistake is discovered, it can be corrected on the readings screen, but since the cursor does not usually move into this field, the <F12> key (prev field) must be used to back into it. The cursor must first be on the correct allergen row and can be moved there by the up and down arrow keys.

The system is currently set up so that the readings screen cannot be left unfilled. Entries for each allergen must be made, including either the Not Read code, or all other data fields. The <Next> key will not bring up the exit screen unless all data have been completed. The PF4 key will allow going to the exit screen early, provided that the data that has been entered is consistent. This should be an emergency practice only since partial data is not good data in this test.

After all data on the readings screen have been entered, press the <Next> key to display the results screen.

NOTE: Allergy sample includes all examinees ages 6-19 and even sample numbers ages 20-59. When the full system is operating, this will work automatically. For the training period the system will take sample numbers for anyone ages 6-59 including odd numbers for those 20-59 years.

MEMORANDUM

Date 4 April 1988
From Computer Systems Analyst
Subject Detail Design for the Automated Collection System
for the NHANES-III Allergy Skin Test Data
To Chief, Computer Systems and Programming Staff, DHES

INTRODUCTION

The automated system for collection of allergy data in NHANES-III is implemented under the Oracle data base software. The general design of 31 March 1988 describes the allergy skin test and general data collection system features. This design discusses system details.

DATA BASE DESIGN

Two data tables and three look-up tables are used in this application. The first data table, ALG_SPINFO, contains one row per examinee and has as columns the NCHS# (primary key), and a field for each exclusion criterion. Every examinee must pass the safety requirements before the test is given, so everyone sampled, even excluded people, have an entry (row) in this table.

Table name ALG_SPINFO

Columns	Screen Field	Data Type	Field Length
NCHS	NCHS#: examinee's number	Character	7
ECZEMA	Answer to eczema question	Character	1
WHEEZING	ANSWER TO BREATHING PROBLEMS Q.	CHARACTER	1
REACTION	Answer to allergy reaction q.	Character	1

The other data table, ALGDATA, contains entries only for tested persons and has one row per allergen, or 12 rows per person. This table collects reaction data for each allergen as shown below. Its primary key consists of both the NCHS number, to identify the examinee, and the allergen sequence number, to identify the allergen.

Table name ALGDATA

Columns	Screen Field	Data Type	Field Length
NCHS_NO	NCHS#: examinee's number	Character	7
ALERGSEQ	Allergen Sequence Number	Character	2
ARM	Arm tested for this allergen	Character	1
WHEALEN	Wheal Length	Character	3
WHEALWID	Wheal Width	Character	3
CONFLU	Confluence code	Character	1
FLARELEN	Flare Length	Character	3
FLAREWID	Flare Width	Character	3
NOREAD	Reason Not Read Code	Character	1
LAPSETIM	Minutes, injection to reading	Character	3

The following screen items are taken from data base tables: the names of tested allergens, the arm in which each is injected when the protocol is followed, and the list of reasons an allergen was not tested. The allergen names are stored in a table called ALLERGENS; the arm codes in the ALG_ARM table; and the reasons for not testing in the ALG_NOINJECT table. These are the look-up tables.

Each allergen is associated with a unique sequence number. If the allergens used in the survey change, old sequence numbers must not be reused, but new ones assigned instead. The current ALLERGENS table is shown below. The sequence number field, the primary key, is called ALERSEQ and for now has values assigned in the order of testing.

Table name ALLERGENS

Columns	Screen Field	Data Type	Field Length
SCREENAM	Allergen name shown on screen	Character	11
ALERSEQ	Allergen sequence number	Character	2
FULLNAM	Full name of allergen	Character	25

Current contents:

Full Allergen Name	Screen Name	ALERGSEQ
Negative Control	Neg. Contl.	01
White Oak	White Oak	02
Cat	Cat	03
D. Farinae (house mite)	Mite	04
Alternaria Alternata	Alternaria	05
German, American Cockroach	Cockroach	06
Perennial Rye	Rye Grass	07
Short Ragweed	Ragweed	08
Bermuda Grass	B. Grass	09
Russian Thistle	R. Thistle	10
Peanut	Peanut	11
Positive Control	Pos. Contl.	12

In the present testing protocol, both arms are injected, so selection from the ALG_ARM table comes only from column B. The protocol has changed several times during survey pretesting. The allergy sequence number is the primary key.

Table name ALG_ARM

Columns	Screen Field	Data Type	Field Length
ALERSEQ	Allergen sequence number	Character	2
B	Code when Both arms are used	Character	1
R	Code when only Right arm used	Character	1
L	Code when only Left arm used	Character	1

Current contents:

ALERSEQ	B	R	L
01	L	R	L
02	L	R	L
03	L	R	L
04	L	R	L
05	L	R	L
06	L	R	L
07	R	R	L
08	R	R	L
09	R	R	L
10	R	R	L
11	R	R	L
12	R	R	L

The ALG_NOINJECT table can be updated as needed, but currently has these characteristics.

Table name ALG_NOINJECT

Columns	Screen Field	Data Type	Field Length
REASONCODE	Code for reason not tested	Character	1
TEXT	English version of code	Character	30

Current contents:

REASONCODE	TEXT
4	= No allergen or supplies
7	= SP refused or had to leave
9	= Any other reason

SCREEN DESIGN

The first screen, the Introductory screen, serves to verify identity of the examinee and the test administrator. This screen looks the same in all MEC automated data collection systems. Allergy Injections or Allergy Readings become choices in the procedures section only if the examinee is a member of the allergy subsample. Selecting the Allergy Injections procedure begins the test and brings up the exclusion screen; selecting Allergy Readings brings up the data screen.

The second screen, called the EXCLUSION screen, presents the three instances that might exclude an examinee from testing for safety reasons even though he is a member of the allergy sample. These are presented as questions to which the health technician determines answers either by observation or by asking the examinee.

The third screen, called the INJECTION screen, is used to record which arm is injected with each allergen, and the reason any particular allergen was not tested. When the screen appears, the protocol for testing will be displayed, the left arm shown for the first six allergens, the right arm for the last six. If the examinee has both arms and there is no deviation from this protocol, there need be no data entry on this screen. If one or more allergens are not tested for any reason, or if the testing protocol is altered, the changes should be entered on this screen while injections are being done and the information is fresh.

The fourth screen, called the DATA screen, is used to enter the reaction results.

The final screen, called the ~~EXIT~~^{Results} screen, is used to enter a code for the automated control system to define whether this examinee has completed the full exam or should be rescheduled, and to enter any comments about the test. → Reason for no or incomplete test appears on a second screen

Leaving the injection screen will cause the ~~EXIT~~^{results} screen to appear, closing the test for this person. After 15 minutes have passed, the technician can reopen the test by entering the examinee's number again on the introductory screen and selecting the Allergy Readings procedure to bring up the data screen for recording reactions. Leaving the data screen will also cause the ~~EXIT~~^{results} screen to appear, where the ~~scheduling code~~ can be updated.

Screen layouts are described on the following pages.

Data entry passes from screen to screen under program control as described in the notes later in this memo.

The Introductory and ~~EXIT~~^{Results} screens, common to all data collection systems in the MEC, are documented elsewhere.

MEMORANDUM

Date 31 March 1988
From Computer Systems Analyst
Subject General Design for the Automated Collection System for
the NHANES-III Allergy Skin Test Data
Third revision, after Tampa pre-test
To Chief, Computer Systems and Programming Staff, DHES

Allergy Skin Testing will be done in NHANES-III to measure reactions to these 12 allergens:

negative control; white oak; cat; mite; alternaria; German cockroach; rye grass; ragweed; Bermuda grass; Russian thistle; peanut; and positive control.

TEST CONTENT AND PROTOCOL

Testing is done as follows: the technician, using a template, places a drop of each allergen on the examinee's arms (6 drops on one arm, the other six on the other arm), then pricks the arms under each drop, and wipes off the allergens. After 15 minutes have passed, the technician reads the reactions and records these findings for each allergen:

which arm was tested, right or left;
length and width of both the wheal and flare of each reaction, in millimeters recorded to 3 digits without decimals (000-150);
confluence, a yes/no code as to whether or not the reactions run together; and
the lapse time between the allergen injection and the reading of the reaction, targeted at 15 minutes.

The subsample of examinees to be tested includes all those ages 6 to 19 years, and the half-sample of persons ages 20-59 years who do not receive the Central Nervous System test. Persons having breathing problems or severe eczema on both arms at exam time, or who have had severe reaction to past allergen skin testing will be excluded.

SYSTEM DESIGN

The purpose of the automated data collection system is to provide a faster and more accurate data collection tool than a pencil-paper system, although paper forms must always be available in case the computer system is unavailable for any reason. The automated system should work in the following way.

When the examinee comes into the testing area, the technician will verify his proper identity (Sample Person Number, name, age, and sex) with data in the automated system files. The technician will also validate his own number in the automated system. The system will check that the examinee is a member of the allergy sample, and force checking of exclusion criteria, closing the test for excluded persons. If the test is not done for any reason, the technician will enter an

explanatory code. There will be a means of closing the exam if the examinee is unable to continue after it has begun. When reactions are read, the technician will key the findings. During the lapse time between injection and reading, other examinees could be injected or read; the ability to close and reopen the system during testing of the same person will be needed.

Allergens will always be tested in the same fixed order. This order must be the same as the order in which data are recorded, and currently follows the list of allergen names above.

For every sample person, the allergy output should contain either all readings, or no readings and a reason. There may be partial tests for some persons for various reasons, however, and fields should be included for each allergen to explain why it was not-tested and/or why it was not read.

The allergy test will not be replicated. No imputations are needed. The data fields entered should be range-checked. Consistency editing is needed to check that entered data are accurate and complete for each allergen, and that missing data are explained by a code indicating why they were not collected. ~~Two types of "missing data" codes are required, one for each allergen and one for the entire test.~~

The Allergy Skin Test data collection is ideally suited to the Oracle data base software system. About three screens should be required to collect allergy data which can be stored in Oracle tables.

QUALITY CONTROL

Reliable testing requires quality in the following areas:

- supply of allergens
- injection of the proper sample persons
- adherence to testing protocol
- recording of accurate findings

The automation system cannot assist in quality control over the allergen supply. It will offer data collection screens only for allergy sample examinees, and collected data can be reviewed for sample completion. It can encourage adherence to testing procedures by making data entry as easy as possible and by automatically keeping track of each stage of testing for each examinee. While incorrect data entry cannot be entirely prevented, the system can reduce recording errors by making range checks, field consistency edits, and edits for data completion during the keying process.

Mary Dudley

Mary Dudley

cc: Peter Gergen

December 1, 1987

User Document for Allergen Skin Test V0.1

The Allergen Skin Test Automation System is made up of five screens: the introductory screen, the exclusions screen, the injection screen, the readings screen, and the exit screen. The examinee's name and NCHS number are displayed at the top of each screen. The keys and their functions are described below.

Keys:

The <Return> key moves the cursor to the next data entry field on the same screen.

The <up arrow> and <down arrow> keys move the cursor from line to line on screens where rows are shown.

The <Prev Field> key (F12) moves the cursor to the previous field on the readings screen. It has no function on the exclusions and injection screens.

The <Next> (Next Screen) key is used to move to the next screen.

The <Prev> (Prev Screen) key is used to move from the readings screen back to the injections screen. On other screens, it has no function.

The <Select> key puts an "X" in the field in which the cursor is positioned. It is used only on the introductory screen, to select the Allergen Skin Test exam (or Body Measurements), and on the exit screen, to select options for exam completion.

The <Insert Here> key is used only on the readings screen, and allows the technician to enter row lengths and widths of "000" and Confluent code "N" with a single key stroke when the cursor is positioned at the Wheal Length, or to enter a lapse time of "015" minutes with one key stroke when the cursor is positioned at the Lapse Time field.

The <PF4> key is used to move to the exit screen. It will be most useful on the injection screen, when one examinee has been injected and is waiting for reactions, and the technician wants to close his exam and begin the test for someone else.

The <space bar> is used to clear out erroneous data in a field.

The <Next>, <Prev>, and <PF4> keys usually need to be pressed twice before their action is fully taken. The first press will display a message at the bottom of the screen that requires acknowledgement. The second press acknowledges the message and brings up the next, previous, or exit screen as appropriate.

Screens:

The first screen displayed is the introductory screen, and the last is the exit screen. These screens are the same in all MEC applications, and are documented separately.

After selecting the Allergen Skin Test on the introductory screen, the exclusions screen will be displayed. All three questions on this screen must be answered by "Y" (yes) or "N" (no). If any answer is "Y", the examinee is excluded from testing and the next screen to be displayed will be the exit screen. If the exam is being restarted for an examinee who has been injected but not yet

prevent inadvertent skipping of one or more of these questions, and to ensure examinee safety. When all answers have been entered or are redisplayed, press the <Next> (Next Screen) key to move to the injection screen.

The injection screen will be displayed after the exclusions screen, even for restarted exams. If the usual injection protocol is being used (first 6 injections on the left arm, last 6 on the right), and all allergens are injected, no entry is needed on this screen, even the first time it is presented for the examinee. If the injection protocol does not follow the usual pattern, and/or if one or more allergens are not injected, the fields for arm and/or no injection codes should be corrected for the appropriate allergens. Data on this screen will be recorded as shown after any changes. The redisplay of this screen for an examinee to be read serves to refresh the technician's memory about protocol deviations and injections not done. Arm codes are "L" for left and "R" for right. Codes for allergens not injected are shown on the screen. If the examinee has just been injected and the technician wishes to close this data entry during the waiting period, press the <PF4> key to bring up the exit screen. If the examinee has finished the waiting period and is now to have reactions read, press the <Next> key to display the readings screen. The names and sequence numbers of allergens cannot and must not be updated. Since the <Prev Field> (F12) key is not defined for this screen, a correction to the Arm code when the cursor is placed at the No Injection field on the same line requires moving the cursor to another line and back again using the <up arrow> and <down arrow> keys.

The readings screen requires the most keying by the technician. Certain program features have been included to reduce key strokes.

Lengths and widths: entries can be 0 to 120. If a reaction is 3 mm., enter the "3"; the field will be padded to the left with zeros when the <Return> key is pressed. If a reaction is 15 mm., enter "15" and one zero will be padded to the left. If a reaction is 101 mm., all three digits must be entered. A width cannot be greater than a length. If 0 is entered for a length, the corresponding width of zero will appear and need not be entered. A width greater than a length will cause the cursor to move back to the length field in case it is the one needing correction. If it is not, press the <Return> key to move to the width field and correct all three digits. Once padding has been done, corrections on padded fields require that all three digits be updated. A length or width that cannot be determined can be entered as "888" but all three eights must be keyed. Otherwise padding will take effect and the field will look like an entry of "008". If the examinee refused to allow a reading to be done or if it is not done for some other reason, press the <Return> key when the cursor is positioned at the wheal length field without entering a number; this will cause the cursor to move to the Not Read field where a code can be entered. The Not Read field usually is skipped in normal data entry, and this is the best way to get to it. If data are entered and later found to be on an allergen not read, blank out the wheal length and press <Return> to go to the Not Read code; after its entry, pressing <Return> will clear out the previous data. If Not Read is entered and later found to be keyed on the wrong allergen, it must be cleared by the space bar before reading data are entered.

Often there is no reaction to most allergens. When the cursor is placed at the wheal length, press the <Insert Here> key to get zeros in both lengths and widths, "N" in confluent, and move the cursor to the lapse time field.

it is not possible to decide, ~~code~~ ~~of~~ ~~them~~
the wheal and flare lengths are all zero, the confluent code should
be entered as "N". If the wheal and flare widths are all "888",
the confluent code will be made "U" regardless of what was entered.

~~Lapse time: entries should be 10-20 minutes. The field is three~~ ⁿ
digits, and will be left-padded with zeros if one or two digits
are entered. If the elapsed time between injections and readings
is 15 minutes as targeted, the keyer can press the <Insert Here>
key when the cursor is positioned at the lapse time field and
the value "015" will be put into the lapse time with one key stroke.

The arm code for each allergen is expected to be correctly entered
on the injection screen, when injections are done. If a mistake
is discovered, it can be corrected on the readings screen, but
since the cursor does not usually move into this field, the <F12>
key (prev field) must be used to back into it. The cursor must
first be on the correct allergen row and can be moved there by the
up and down arrow keys.

The system is currently set up so that the readings screen cannot
be left unfilled. Entries for each allergen must be made, including
either the Not Read code, or all other data fields. The <PF4>
and <Next> keys will not bring up the exit screen unless all data
have been completed. In an emergency, the <Prev> key can be used
to bring up the injection screen, and from that screen the <PF4>
key can be used to bring up the exit screen. This is an emergency
practice only, since partial data is not good data in this test.

After all data on the readings screen have been entered, either
the <Next> or <PF4> keys can be used to display the exit screen.

Appendix B
Screen by Screen Instructions for the Allergy Component

Introduction

Technician

Job# 1001
Name Bob Murphy

Examinee

Sample# 6666666
Name tyke
Age 6 Years/Months Y
Sex M

Procedures

- Allergy Injections
- Allergy Readings
- Body Measures
- Body Measures

Char Mode: Replace Page 1

Count: *4

Introduction screen. Selecting "Allergy Injections" from this screen will bring up the questions, and then, if the SP is not excluded, the injection screens (these follow) and results screens. Selecting "Allergy Readings" will bring up the reading screen and its results screens.

Name tyke NCHS# 6666666

Allergy Exam _____

Are you now having problems breathing? _____

1 Yes _____

2 No _____

8 No data collected _____

2

Allergy Exam _____

Do you usually have breathing problems? _____

- 1 Yes _____
- 2 No _____
- 8 No data collected _____

1

Name tyke NCHS# 6666666

Allergy Exam

Have you had a past severe reaction to allergen skin testing?

- 1 Yes
- 2 No
- 8 No data collected

2

Name tyke NCHS# 6666666

Allergy Exam _____

Observe:

Does this sample person have severe eczema or infection on both arms?

1 Yes

2 No

8 No data collected

2

Name tyke

Sample# 66666

Allergy Interview

Technician 1001

Transaction completed -- 1 records processed
Press any function key to acknowledge message

This screener appears after the questions, while the software decides whether the examinee has been excluded or not. Just press the <Return> key and move on (or <Next> key).

name type _____

SAMPLE# 666666

alg.inj.1

INJECTIONS SCREEN

Allergen	Seq #	R=1 L=2 Arm	Reason no Injection
Neg. Contl.	01	L	-
White Oak	02	L	7
Cat	03	L	-
Mite	04	L	-
Alternaria	05	L	-
Cockroach	06	L	-
Rye Grass	07	R	-
Ragweed	08	R	-
B. Grass	09	R	-
R. Thistle	10	R	-
Peanut	11	R	-
Pos. Contl.	12	R	-

Codes for
Reason no
Injection

4 = No allergen or supplies
7 = SP refused or had to leave
9 = Any other reason

Char Mode: Replace Page 1

Count: 12

If the injections are all given, 6 on each arm as the protocol dictates, no entry is needed on this screen. Enter "arm" codes only if different from those shown above; enter "no injection" codes only for those allergens not given to the examinee. Press <Next> key to advance the screen.

Name tyke Sample# 6666666

Examination results

Select one

- Injections done
- Injections incomplete
- Injections not done

Comments:

Char Mode: Replace Page 1

Count: *3

Results screen for allergy injections. If the injections were done, the next screen will be the introduction screen again. If incomplete or not done, the next screen will be the one on the following page. To make one of these selections, move the cursor up or down using the up and down arrow keys. When the cursor is next to the proper choice, press <Select>, enter a comment if desired, and press <Next> to advance the screen.

Name tyke

Sample# 6666666

Termination results

Select one

- No allergens or other supplies
- Insufficient time available or room not available
- Examinee refused or uncooperative
- Examinee medically excluded for safety
- Other

Comments:

Char Mode: Replace Page 1

Count: *5

Screen for reasons for incomplete test or no test. Select a choice as on the previous screen, enter a comment if needed, and press <Next> to return to the introductory screen.

name tyke

Sample# 6666666

alg.read

READINGS SCREEN

U=8
Y=1 N=2

4=tech. problem
7=refused, let
9=other reason

Allergen	Seq #	R=1 L=2 Arm	----Flare----		Con flu ent	----Wheal----		Lapse Time	Not Read
			Length	Width		Length	Width		
Neg. Contl.	01	L	0	0	2	0	0	015	
White Oak	02	L	0	0	2	0	0	015	7
Cat	03	L	0	0	2	0	0	015	
Mite	04	L	0	0	2	0	0	005	
Alternaria	05	L	0	0	2	0	0	020	
Cockroach	06	L	0	0	2	0	0	015	
Rye Grass	07	R	0	0	2	0	0	015	
Ragweed	08	R	0	0	2	0	0	015	
B. Grass	09	R	0	0	2	0	0	015	
R. Thistle	10	R	0	0	2	0	0	015	
Peanut	11	R	0	0	2	0	0	015	
Pos. Contl.	12	R	0	0	2	0	0	015	

Char Mode: Replace Page 1

Count: 12

This is the readings screen on which reaction data are entered. See operating instructions for use of keys on this screen. Note: if a message "Query caused no records to be retrieved" appears at the bottom when this screen first comes up, it means that the injections screen data were not stored for this person, and the exclusion questions may not have been asked. Press <Prev> to return to the intro screen and select "Allergy Injections" instead. Also: if an entry is to be changed, type over all positions or serious errors could result.

Name tyke Sample# 6666666

amination results

Select one

- Readings done
- Readings incomplete
- Readings not done

Comments:

Char Mode: Replace Page 1

Count: *3

Results screen for readings. Works just like the one for injections.

Name tyke Sample# 6666666

Examination results

Select one

- No allergen or other supplies
- Insufficient time available or room not available
- Examinee refused or uncooperative
- Examinee medically excluded for safety
- Other

Comments:

Char Mode: Replace Page 1

Count: *5

Reasons for incomplete or no readings. Note that for now these reasons are the same as those for no injections, and the screen works the same way.

Appendix C

NHANES III Allergy Component Checklist

NHANES III ALLERGY COMPONENT CHECKLIST

Medical Exclusion

- Ask SP re breathing problems and previous severe reaction
- Check forearms for skin infection

Administration of Allergen Skin Tests

- Describe procedures to SP
- Put on gloves
- Ask SP to clean forearms
- Using template, mark 12 sites
- Number the sites
- Place drops on sites, 1, 2, 3
- Prick sites 1 - 3
- Set timer to 15 minutes
- Wipe sites 1 - 3
- Repeat dropping/pricking/wiping for sites 4 - 6, 7 - 9, and 10 - 12

Reading the Reactions

- When timer goes off, circle flares and wheals of significant reactions
- If diameter 3 mm+, measure width and length of flare and wheal

Recording the Results

- Enter results on screen or on hard copy Allergy Test Form

After the Readings

- Ask SP to clean arms
- Record time out on Allergy Daily Log

Appendix D
Spanish Version - Allergy Data Form

PRUEBA DE ALERGIA (EADAES 6-19 TODOS Y 20-59 PARES)

STAFF NO. _____ NCHS ID NO. _____

1.	Ahora, ¿está teniendo problemas respirando?	1 <input type="checkbox"/> S (Q2)	2 <input type="checkbox"/> N (Q4)
2.	Usualmente, ¿tiene problemas para respirar?	1 <input type="checkbox"/> S (Q3)	2 <input type="checkbox"/> N - Excluya
3.	Su actual problema para respirar, ¿es peor que lo usual?	1 <input type="checkbox"/> S - Excluya	2 <input type="checkbox"/> N (Q4)
4.	En el pasado, ¿ha tenido una reacción severa, a una prueba de alérgen en la piel?	1 <input type="checkbox"/> S - Excluya	2 <input type="checkbox"/> N
5.	DOES SAMPLE PERSON HAVE SEVERE ECZEMA OR INFECTION ON BOTH ARMS?	1 <input type="checkbox"/> S - EXCLUDE	2 <input type="checkbox"/> N

IF ONLY ONE ARM USED, INDICATE WHICH ARM:

RIGHT LEFT (INDICATE REASON BELOW FOR USE ONE ARM)

	FLARE				WHEEL			*REASON FOR NO INJECTION OF THIS ALLERGEN
	LENGTH (mm)	WIDTH (mm)	CONFLUENT Y	CONFLUENT N	LENGTH (mm)	WIDTH (mm)	**MINUTES	
1. NEGATIVE CONTROL	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
2. WHITE OAK	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
3. CAT	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
4. MITE	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
5. ALTERNARIA	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
6. GERMAN COCKROACH	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
7. RYE GRASS	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
8. RAGWEED	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
9. BERMUDA GRASS	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
10. RUSSIAN THISTLE	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
11. PEANUT	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___
12. POSITIVE CONTROL	___	___	<input type="checkbox"/>	<input type="checkbox"/>	___	___	___	___

*REASON NO INJECTION FOR SPECIFIC ALLERGEN:

- 4 NO ALLERGEN OR SUPPLIES
- 7 REFUSED DUE TO REPORTED ALLERGY
- 9 REFUSED - OTHER REASON

**Minutes from administration to reading (only if differs from 15 minutes ± 5 minutes)