

BASELINE MEDICAL HISTORY

1 Background and Purpose

The purpose of the Medical History Form is to assess co-morbidity and identify severe problems that would necessitate referral. The form contains general information on past medical history; questions regarding: angina or chest pain, cardiovascular procedures, and pulmonary disease; and a general review of systems. The Baseline Medical History form assesses prevalent cardiovascular morbidity in the CHS cohort, while the Surveillance form elicits incident events and identifies information (hospital and M.D.'s names, date) for subsequent confirmation of the event.

The study forms are closely based upon both the Atherosclerosis Risk in the Community (ARIC) Study and the Systolic Hypertension in the Elderly Program (SHEP) collection forms. The past medical history questions are derived from the SHEP Questionnaire. The congestive heart failure questions are taken directly from the ARIC Protocol. The Rose Questionnaires on angina and intermittent claudication are standardized and have been used in multiple studies sponsored by the NIH. The respiratory questions are a subset of the American Thoracic Society ATS-DLD-78 Standard Respiratory Questionnaire (Am Rev Respir Dis 1978; 118 (Part 2): 7-53), with supplementary questions about morbidity from respiratory diseases during the previous year taken from Form 31 (July, 1986) of the NHLBI funded, multicenter Lung Health Study.

2 Definitions and Alerts

2.1 Events

A detailed discussion of prevalent vs incident events is found in the "Protocol for CHS Events". The definition of a prevalent cardiovascular event is adjudicated depending on confirmation by personal physician or hospital records.

A positive response to the cardiovascular procedure questions (Questions 12-19) is taken as confirmation of that procedure in the absence of physician and hospital record documentation.

- O Angina is defined as being present in participants that answer as follows:
 - Question 20 = yes, and
 - Question 21 or 22 = yes, and
 - Question 23 = stop or slow down," and
 - Question 24 = relieved, and
 - Question 24A = ten minutes or less, and
 - Question 25 = sternum (1 - Upper or middle, or 2 - lower), or 3 - left anterior chest and 4 - left arm.
- O Pain of possible infarction is defined as being present in participants who answer as follows:

Question 26 = yes

NOTE: When the answer to question 26A "Did you see a doctor because of this pain?" is negative, especially in the presence of a positive Rose Questionnaire, the participant should be seen by the clinic physician at that visit for subsequent disposition.

- O Congestive heart failure is suggested when:

Question 27 = yes, and
Question 28 = yes, and
Question 29 = yes, and
Question 29A = yes.

Confirmatory evidence is obtained from participant's reported history as outlined in the protocol for CHS events.

- O Claudication is defined as positive in participants who answer as follows:

Question 30 = yes, and
Question 31 = no, and
Question 32 includes calf, and
Question 33 or 34 = yes, and
Question 35 = no, and
Question 36 = stop or slow, down, and
Question 37 = relieved, and
Question 37A = ten minutes or less.

2.2 Alerts

At the end of the clinic visit, positive responses of potential medical significance are summarized on the CHS Exit Summary form by a computer algorithm. Positive symptoms and/or signs which should trigger medical follow-up or referral are verified during the Exit Summary Interview.

2.3 Definitions

- O Physician A licensed medical doctor, MD, or osteopath, DO.
- O The London School of Hygiene Questionnaire (The Rose Questionnaire) is administered according to the standardized instructions and interviewer training recommended by Rose and Blackburn.

NOTE: The CHS form allows for a response not included in the original questionnaire ("Never hurries or walks uphill") to Questions 21 and 33: "Do you get it when you walk uphill or hurry?"

- O The word "never" is interpreted literally and does not include responses such as "almost never" or "rarely".

3 **Methods**

- 3.1 The Medical History Form is a self-administered questionnaire which is left with the CHS Participant at the end of the Home Visit. The participant is asked to complete the form and bring the completed questionnaire to the Clinic Visit.

When an interviewer perceives that the participant will not be able to complete the self-administered form, the form(s) should be administered by an interviewer in the home or in the clinic.

- 3.2 During the Clinic Visit a CHS Interviewer reviews the form to identify any questions which were not answered, were marked in an unclear fashion, or were skipped inappropriately. (Participant need not be present during the review.)

The responses to Question 25 must be coded using the information on Interviewer Card 19.

When inconsistencies or errors are noted, the CHS Interviewer discusses these questions with the participant to determine the correct response(s).

- 3.3 If a participant fails to bring a completed questionnaire to the clinic Visit, another copy of the form will be given to the participant and time allocated for completion of the form.
- 3.4 When the participant is unable to complete the questionnaire, a CHS Interviewer will administer the questionnaire.
- 3.5 The following guidelines are provided to assist the interviewer and/or analyst regarding the interpretation on the codes.

- O Introductory Script: I would like to ask you a few questions about your health, especially your heart and circulation. Many of these questions may seem repetitious, but we are trying to be thorough.

- 3.6 Question 1 to 4 - Has a doctor ever told you that you had:

- O Read each condition (1-4) and wait for a response before continuing to the next condition.
 - ! Myocardial infarction or heart attack
 - ! Congestive heart failure
 - ! Intermittent claudication

! Angina

O Record the participant's responses.

! Code "1 - Yes" when the participant indicates s/he has had a diagnosis of the condition.

- When the participant responds "Yes":

! Code "0 - No" when the participant indicates s/he has never had a diagnosis of the condition.

! Code "9 - Don't Know/Refused" when the participant indicated s/he did not know or refused to answer.

O Question A: What was the doctor's name and address?

! When condition is coded "1 - Yes", record the doctor's name and address.

! When the participant is unable to supply the complete information, record all which is available.

O Question B: Were you hospitalized for your (NAME OF CONDITION)?

! Code "1 - Yes" when the participant has been hospitalized for one of the conditions.

! Code "0 - No" when the participant was not hospitalized for one of the conditions.

! Code "9 - Don't Know/Refused" when the participant indicated s/he did not know or refused to answer.

O Question C - What was the hospital's name and address.

! When Question C is coded "1 - Yes", record the hospital's name and address.

! When the participant is unable to supply the complete information, record all which is available.

3.7 Question 5 to 11 - Has a doctor ever told you that you had:

O Read each condition (5-11) and wait for a response before continuing to the next condition.

- ! High blood pressure
- ! Rheumatic heart or heart valve problems
- ! Diabetes
- ! Atrial fibrillation
- ! Deep venous thrombosis or blood clots in your leg
- ! Pulmonary embolus or blood clots in your lungs
- ! Other heart or circulatory problems

O Record the participant's responses.

- ! Code "1 - Yes" when the participant indicates s/he has had a diagnosis of the condition.
- ! Code "0 - No" when the participant indicates s/he has never had a diagnosis of the condition.
- ! Code "9 - Don't Know/Refused" when the participant indicated s/he did not know or refused to answer.

O Question 12 to 19 Coronary and Cardiovascular Procedures

- ! Script: Have you ever had:
 - Coronary bypass surgery?
 - Other heart surgery?
 - Carotid endarterectomy which is surgery on the blood vessels of your neck??
 - A bypass procedure on the arteries of your legs?
 - A repair of an aortic aneurysm?
 - A pacemaker implant?
 - An angioplasty of the coronary arteries which is a dilation of the arteries of the heart with a balloon?
 - An angioplasty of the lower extremity arteries which is a dilation of the arteries of the leg with a balloon?
- ! Code "1 - Yes" when the participant indicates s/he has had the procedure.
- ! Code "0 - No" when the participant indicates s/he has never had the procedure.
- ! Code "9 - Don't Know/Refused" when the participant indicated s/he did not know or refused to answer.

3.8 Question 20 to 26 Rose Questionnaire for Angina and Possible Myocardial Infarction

O Question 20 - Have you ever had any pain or discomfort in your chest?

! Code "1 - Yes" when the participant reported ever having had the symptom, no matter how infrequent, how long ago, or how seemingly unrelated to the heart.

! Code "0 - No" when the participant never had the symptom.

NOTE: If No, skip to 27.

O Question 21- Do you get it when you walk uphill or hurry?

! Code "1 - Yes" only when the participant reported that the symptom occurred while walking uphill or hurrying.

! Code "0 - No" when the symptom did not occur walking uphill or hurrying.

This includes responses which indicate the symptom occurred during other activities, but not while walking uphill or hurrying.

! Code "A - Never hurries or walks uphill" when the participant states they never hurry or walk uphill.

O Question 22 - Do you get it when you walk at an ordinary pace on the level?

! Code "1 - Yes" when the participant reported that the symptom occurred walking at a normal pace on level ground.

! Code "0 - No" when the symptom did not occur walking at a normal pace on level ground.

This includes responses which indicate the symptom occurred during other activities, but not while walking at a normal pace on the level.

O Question 23 - What do you do if you get it while you are walking?

This is an open ended question with "stop" and "slow down" being positive responses.

! Code "1 - Stop or slow down" when the participant states that s/he stops or slows down in response to the pain.

NOTE: Record "stop or slow down" when participant "continues at same pace" after taking nitroglycerin. This includes responses such as "I suck

on my pill and keep on going."

- ! Code "2 - Continue at the same pace" when the participant indicates that they continue on as before the pain occurred without taking any other action. See Note above.

O Question 24 - If you stand still, what happens to it?

- ! Code "1 - Relieved" when the pain/discomfort goes away when the participant stops walking.

- ! Code "2 - Not relieved" when the pain/discomfort does not go away when the participant stops walking.

NOTE: If pain/discomfort is not relieved, skip to 25.

O Question 24A - How soon?

This is an open ended question. 10 minutes or less is considered a positive response.

- ! Code "1 - 10 minutes or less" when the pain/ discomfort goes away within 10 minutes of when the participant stops walking.
- ! Code "2 - More than 10 minutes" when the pain/ discomfort takes more than 10 minutes to go away after the participant stops walking.

O Question 25 - Will you show me where it was?

This item is coded using the following information which is also contained on Interviewer Card 19. (CHECK YES FOR ALL THAT APPLY)

- ! Imagine a suit vest with buttons down the front. Pain involving the sternum is pain touching the button line or midline on the chest of the participant. Pain involving the upper/middle sternum is midline pain above where you would estimate the nipple line to be. Pain involving the lower sternum is midline pain below the nipple line.

Pain in the left anterior chest is any pain above the rib margin on the left side of the front of the vest. That is, the area bounded by the seam joining the front and back of the vest on top of the shoulder, the open sleeve of the vest, the seam joining the front and back of the vest under the armpit, the lower border of the rib cage, the button line to the neck, and a line along the collar bone joining the button line to the seam on top of the shoulder.

Pain in the left arm is pain anywhere below the left open sleeve of the

vest.

Interviewer should make the appropriate coding determinations based on participants response.

- ! Sternum (upper or middle)
- ! Sternum (lower)
- ! Left anterior chest
- ! Left arm
- ! Other, specify

! Code "1 - Yes" when the participant had pain/discomfort in the region/area.

! Code "0 - No" when the participant did not have pain/discomfort in the region/area.

O Question 26 - Have you ever had a severe pain across the front of your chest lasting for half an hour or more?

! Code "1 - Yes" when the participant reported ever having had the symptom, no matter how infrequent, how long ago, or how seemingly unrelated to the heart.

! Code "0 - No" when the participant did not have the symptom.

Note: If No, skip to Question 27.

O Question 26A - Did you see a doctor because of this pain?

! Code "1 - Yes" when the participant saw a physician because of the chest pain.

! Code "0 - No" when the participant did not see a physician because of the chest pain.

NOTE: If No, skip to 27.

O Question 26B - What did your doctor say it was?

! Code "1 - Angina" when the participant said the diagnosis was angina.

! Code "2 - Heart attack" when the participant said the diagnosis was a heart attack.

- ! Code "3 - Other" when the participant said the diagnosis was something other than angina or heart attack. Specify the diagnosis in the space provided on the screen.

3.9 Question 27 to 29 - Questionnaire for Congestive Heart Failure

- O Question 27 - Have you ever had to sleep on 2 or more pillows to help you breathe?

- ! Code "1 - Yes" when the participant reported ever having had the symptom, no matter how infrequent, how long ago, or how seemingly unrelated to the heart.

- ! Code "0 - No" when the participant did not have the symptom.

- O Question 28 - Have you ever been awakened at night by trouble breathing?

- ! Code "1 - Yes" when the participant had the symptom.

- ! Code "0 - No" when the participant did not have the symptom.

- O Question 29 - Have you ever had swelling of your feet or ankles (excluding during pregnancy)?

- ! Code "1 - Yes" when the participant had the symptom.

- ! Code "0 - No" when the participant did not have the symptom.

NOTE: Minor swelling of feet in hot weather only should not be considered a positive response.

NOTE: If No, skip to 30.

- O Question 29A - Did it tend to come on during the day and go down overnight?

- ! Code "1 - Yes" when the participant had the symptom.

- ! Code "0 - No" when the participant did not have the symptom.

NOTE: Minor swelling of feet in hot weather only should not be considered a positive response.

3.10 Question 30 to 38 - Rose Questionnaire for Intermittent Claudication

- O Question 30 - Do you get pain in either leg on walking?

- ! Code "1 - Yes" when the participant reported ever having had the symptom, no matter how infrequent, how long ago, or how seemingly unrelated to claudication.
- ! Code "0 - No" when the participant never had the symptom.
NOTE: If No, skip to 39.
- O Question 31 - Does this pain ever begin when you are standing still or sitting?
 - ! Code "1 - Yes" when the symptom occurred while standing still or sitting.
 - ! Code "0 - No" when the symptom did not occur while standing still or sitting.
- O Question 32 - In what part of your leg do you feel it?
 - ! Code "1 - Yes, pain includes calf/calves" when the participant indicates the pain includes the calf of one or both legs. This includes responses such as: "the back of my leg(s)" pointing to the back of the leg(s).
 - ! Code "0 - No, pain does not include calf/calves" when the participant indicates the pain occurs somewhere other than the calf/calves of the leg(s).
- O Question 33 - Do you get it if you walk uphill or hurry?
 - ! Code "1 - Yes" only when the participant reported that the symptom occurred while walking uphill or hurrying.
 - ! Code "0 - No" when the symptom did not occur walking uphill or hurrying.

This includes responses which indicate the symptom occurred during other activities, but not while walking uphill or hurrying.
 - ! Code "9 - Never hurries or walks uphill" when the participant states they never hurry or walk uphill.
- O Question 34 - Do you get it if you walk at an ordinary pace on the level?
 - ! Code "1 - Yes" when the participant reported that the symptom occurred walking at a normal pace on level ground.
 - ! Code "0 - No" when the symptom did not occur walking at a normal pace on level ground.

This includes responses which indicate the symptom occurred during other

activities, but not while walking at a normal pace on the level.

O Question 35 - Does this pain ever disappear while you are walking?

! Code "1 - Yes" when the pain sometimes goes away while participant is walking.

! Code "0 - No" when the pain never goes away while participant is walking.

O Question 36 - What do you do if you get it when you are walking?

This is an open ended question with "stop" and "slow down" being positive responses.

! Code "1 - Stop or slow down" when the participant states that s/he stops or slows down in response to the pain.

NOTE: Record "stop or slow down" when participant "continues at same pace" after taking nitroglycerin. This includes responses such as "I suck on my pill and keep on going."

! Code "2 - Continue at the same pace" when the participant indicates that they continue on as before the pain occurred without taking any other action. See Note above.

O Question 37 - What happens to it if you stand still?

NOTE: If pain/discomfort is not relieved, skip to 38.

! Code "1 - Relieved" when the pain/discomfort goes away when the participant stops walking.

! Code "2 - Not relieved" when the pain/discomfort does not go away when the participant stops walking.

O Question 37A - How soon?

This is an open ended question. 10 minutes or less is considered a positive response.

! Code "1 - 10 minutes or less" when the pain/ discomfort goes away within 10 minutes of when the participant stops walking.

! Code "2 - More than 10 minutes" when the pain/discomfort takes more than 10 minutes to go away after the participant stops walking.

O Question 38 - Were you hospitalized for this problem in your legs?

! Code "1 - Yes" when the participant was hospitalized for the leg pain.

! Code "0 - No" when the participant was not hospitalized for the leg pain.

3.11 Question 39 to 67 - Respiratory Symptoms

Interviewers are instructed to follow the actual printed wording for the question, and to accept unequivocal answers as provided by the participant.

The wording of the questions, and the instructions by the interviewer before starting this portion of the interview, lead to simple "yes" or "no" answers. Probing is limited to a repetition of the question when possible, and equivocal answers are recorded as "no".

Have you ever had any of the following?

O Question 39 - Have you ever had attacks of bronchitis?

! Code "1 - Yes" when the participant had bronchitis.

- Bronchitis: several days or weeks of a "chest cold" when yellow or green sputum was coughed up. When the participant saw a physician, the doctor may have prescribed antibiotics.

! Code "0 - No" when the participant never had bronchitis.

NOTE: If No, skip to 40.

O Question 39A - Was it confirmed by a doctor?

! Code "1 - Yes" when the diagnosis was confirmed by a physician.

! Code "0 - No" when the diagnosis was never confirmed by a physician.

O Question 39B - At what age did was your first attack?

! Record the participant's age at first attack.

! When the exact age is not known, an estimate must be made.

O Question 40 - Have you ever had chronic bronchitis?

! Code "1 - Yes" when the participant had chronic bronchitis.

! Code "0 - No" when the participant never had chronic bronchitis.

NOTE: If No, skip to 41.

O Question 40A - Do you still have it?

! Code "1 - Yes" when the participant still has chronic bronchitis.

! Code "0 - No" when the participant no longer has chronic bronchitis.

O Question 40B - Was it confirmed by a doctor?

! Code "1 - Yes" when the diagnosis was confirmed by a physician.

! Code "0 - No" when the diagnosis was never confirmed by a physician.

O Question 40C - At what age did it start?

! Record the participant's age when the chronic bronchitis first began.

! When the exact age is not known, an estimate must be made.

O Question 41 - Have you ever had pneumonia (include bronchopneumonia)

! Code "1 - Yes" when the participant had pneumonia.

! Code "0 - No" when the participant never had pneumonia.

NOTE: If No, skip to 42.

O Question 41A - Was it confirmed by a doctor?

! Code "1 - Yes" when the diagnosis was confirmed by a physician.

! Code "0 - No" when the diagnosis was never confirmed by a physician.

O Question 41B - At what age was your first attack?

! Record the participant's age at first attack of pneumonia.

! When the exact age is not known, an estimate must be made.

O Question 42 - Have you ever had hay fever?

! Code "1 - Yes" when the participant had hay fever.

- Hay fever: any environmental allergens, not just pollen.

! Code "0 - No" when the participant never had hay fever.

NOTE: If No, skip to 43.

O Question 42A - Was it confirmed by a doctor?

! Code "1 - Yes" when the diagnosis was confirmed by a physician.

! Code "0 - No" when the diagnosis was never confirmed by a physician.

O Question 42B - At what age did it start?

! Record the participant's age when the hay fever first started.

! When the exact age is not known, an estimate must be made.

O Question 43 - Have you ever had emphysema?

! Code "1 - Yes" when the participant had emphysema.

! Code "0 - No" when the participant never had emphysema.

NOTE: If No, skip to 44.

O Question 43A - Do you still have it?

! Code "1 - Yes" when the participant still has emphysema.

! Code "0 - No" when the participant no longer has emphysema.

O Question 43B - Was it confirmed by a doctor?

! Code "1 - Yes" when the diagnosis was confirmed by a physician.

! Code "0 - No" when the diagnosis was never confirmed by a physician.

O Question 43C - At what age did it start?

! Record the participant's age when the emphysema first started.

! When the exact age is not known, an estimate must be made.

O Question 44 - Have you ever had asthma?

! Code "1 - Yes" when the participant had asthma.

! Code "0 - No" when the participant never had asthma.

NOTE: If No, skip to 45.

O Question 44A - Do you still have it?

! Code "1 - Yes" when the participant still has asthma.

! Code "0 - No" when the participant no longer has asthma.

O Question 44B - Was it confirmed by a doctor?

! Code "1 - Yes" when the diagnosis was confirmed by a physician.

! Code "0 - No" when the diagnosis was never confirmed by a physician.

O Question 44C - At what age did it start?

! Record the participant's age when the asthma first started.

! When the exact age is not known, an estimate must be made.

O Question 44D - If you no longer have it, what age did it stop?

! Record the participant's age when the asthma stopped.

! When the exact age is not known, an estimate must be made.

O Question 45 - Have you ever had any other chest illness?

! Code "1 - Yes" when the participant had some chest illness not described above. If "1 - Yes", specify the illness in the space provided on the screen.

EXAMPLES:

Tuberculosis	Silicosis
Pulmonary embolus	Spontaneous pneumothorax
Asbestosis	

! Code "0 - No" when the participant has not had any other chest illness.

O Question 46 - Have you ever had any chest operations?

! Code "1 - Yes" when the participant had a chest operation(s). If "1 - Yes",

specify the type of operation in the space provided on the screen.

! Code "0 - No" when the participant has not had a chest operation(s).

O Question 47 - Have you ever had any chest injuries?

! Code "1 - Yes" when the participant had a chest injury(s). If "1 - Yes", specify the type of injury(s) in the space provided on the screen.

! Code "0 - No" when the participant never had a chest injury(s).

O Question 48 - Do you usually have a cough?

! Code "1 - Yes" when the participant usually has a cough.

- Cough includes:
Cough on first smoke
Cough on first going out-of-doors.
- Cough excludes:
Clearing throat

! Code "0 - No" when the participant usually has no cough.

NOTE: If No, skip to 51.

O Question 48A - Do you usually cough as much as 4 to 6 times a day, 4 or more days out of the week?

! Code "1 - Yes" when the participant had a cough as described.

! Code "0 - No" when the participant does not have the cough as described.

O Question 48B - Do you usually cough at all on getting up or first thing in the morning?

! Code "1 - Yes" when the participant usually has a cough as described.

! Code "0 - No" when the participant does not usually have a cough as described.

O Question 48C - Do you usually cough at all during the rest of the day or at night?

! Code "1 - Yes" when the participant usually has a cough as described.

! Code "0 - No" when the participant does not usually have a cough as described.

IF YES TO ANY OF ABOVE (48A-48C) ASK THE FOLLOWING QUESTIONS.

- O Question 49 - Do you usually cough like this on most days for three consecutive months or more during the year?
 - ! Code "1 - Yes" when the participant's cough is present on most days for three consecutive months or more during the year.
 - ! Code "0 - No" when the participant's count is not present for three consecutive months or more during the year.
- O Question 50 - For how many years have you had this cough?
 - ! Record the number of years the participant has had the cough described above.
 - ! When the exact number of years is not known, an estimate must be made.
- O Question 51 - Do you usually bring up phlegm from your chest?
 - ! Code "1 - Yes" when the participant usually has phlegm from the chest.
 - Phlegm includes:
 - Phlegm on first smoke
 - Phlegm on first going out-of-doors
 - Phlegm which is swallowed
 - Phlegm excludes:
 - Phlegm from the nose
 - ! Code "0 - No" when the participant does not usually bring up phlegm.

NOTE: If No, skip to 54.
- O Question 51A - Do you usually bring up phlegm like this as much as twice a day, 4 or more days out of the week?
 - ! Code "1 - Yes" when the participant had phlegm production as described.
 - ! Code "0 - No" when the participant does not have phlegm production as described.
- O Question 51B - Do you usually bring up phlegm at all on getting up, or first thing in the morning?

! Code "1 - Yes" when the participant had phlegm production as described.

! Code "0 - No" when the participant does not have phlegm production as described.

O Question 51C - Do you usually bring up phlegm at all during the rest of the day or at night?

! Code "1 - Yes" when the participant had phlegm production as described.

! Code "0 - No" when the participant does not have phlegm production as described.

IF YES TO ANY OF ABOVE (51A-51C) ASK THE FOLLOWING QUESTIONS.

O Question 52 - Do you bring up phlegm like this on most days for 3 consecutive months or more during the year?

! Code "1 - Yes" when the participant had phlegm production as described.

! Code "0 - No" when the participant does not have phlegm production as described.

O Question 53 - For how many years have you had trouble with phlegm?

! Record the number of years the participant has had the phlegm production described above.

! When the exact number of years is not known, an estimate must be made.

DOES YOUR CHEST EVER SOUND WHEEZY OR WHISTLING:

O Question 54A - Does your chest ever sound wheezy or whistling when you have a cold?

! Code "1 - Yes" when the participant has wheezing/whistling with a cold.

! Code "0 - No" when the participant does not have wheezing/whistling with a cold.

O Question 54B - Does your chest ever sound wheezy or whistling occasionally apart from colds?

! Code "1 - Yes" when the participant has wheezing/whistling other than with a cold.

- ! Code "0 - No" when the participant does not have wheezing/whistling other than with a cold.
- O Question 54C - Does your chest ever sound wheezy or whistling on most days or nights?
 - ! Code "1 - Yes" when the participant has wheezing/whistling most days and/or nights.
 - ! Code "0 - No" when the participant does not have wheezing/whistling most days and/or nights.

IF NO TO ALL ABOVE, SKIP TO 57.

- O Question 55 - For how many years has this been present?
 - ! Record the number of years the participant has had the wheezing or whistling described above.
 - ! When the exact number of years is not known, an estimate must be made.
- O Question 56 - Have you ever had an attack of wheezing that made you feel short of breath?
 - ! Code "1 - Yes" when the participant had wheezing as described.
 - ! Code "0 - No" when the participant never had wheezing as described.

NOTE: If No, skip to 57.
- O Question 56A - How old were you when you had your first such attack?
 - ! Record the participant's age at first attack.
 - ! When the exact age is not known, an estimate must be made.
- O Question 56B - Have you had 2 or more such episodes?
 - ! Code "1 - Yes" when the participant has had two or more episodes of wheezing which caused shortness of breath.
 - ! Code "0 - No" when the participant did not have wheezing as described.
- O Question 56C - Have you ever required medicine or treatment for the attacks?

! Code "1 - Yes" when the participant used medications for the attacks.

- Medicine or treatment includes:
 - Over-the-counter bronchodilators (inhalants to open up the lung passages, such as Primatene Mist)
 - Prescription medications.

! Code "0 - No" when the participant did not use medicines for the attacks.

O Question 57 - Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill?

! Code "1 - Yes" when the participant had shortness of breath as described.

! Code "0 - No" when the participant did not have shortness of breath as described.

NOTE: If No, skip to 62.

O Question 58 - Do you have to walk slower than people of your age on the level because of breathlessness?

! Code "1 - Yes" when the participant had breathlessness as described.

! Code "0 - No" when the participant did not have breathlessness as described.

O Question 59 - Do you ever have to stop for breath when walking at your own pace on the level?

! Code "1 - Yes" when the participant stopped for breath as described.

! Code "0 - No" when the participant never stopped for breath as described.

O Question 60 - Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on the level?

! Code "1 - Yes" when the participant stopped for breath as described.

! Code "0 - No" when the participant never stopped for breath as described.

O Question 61 - Are you too breathless to leave the house or breathless on dressing or undressing?

! Code "1 - Yes" when the participant had breathlessness as described.

! Code "0 - No" when the participant had breathlessness as described.

3.12 Questions 62 to 74 - Immediate Past History (previous 2 weeks)

For positive responses to questions 62-73A, ask follow-up question "Has there been an increase in the frequency or severity of your (NAME OF SYMPTOM)?" If the symptom was not present, skip to next question.

- O Question 62A - Have you been breathlessness or short of breath during the last two weeks?
- O Question 63A - Have you experienced palpitations during the last two weeks?
- O Question 64A - Have you been dizzy during the last two weeks?
- O Question 65A - Have you been fatigued during the last two weeks?
- O Question 66A - Have you felt weak during the last two weeks?
- O Question 67A - Have you been nauseous during the last two weeks?
- O Question 68A - Have you had indigestion during the last two weeks?
- O Question 69A - Have you had chest pain during the last two weeks?
- O Question 70A - Have you had upper abdominal pain during the last two weeks?
- O Question 71A - Have you had a fever during the last two weeks?
- O Question 72A - Have you had muscle aches during the last two weeks?
- O Question 73A - Have you had diarrhea during the last two weeks?
- O Question 74 - Have you seen a physician during the last two weeks?

! Code "1 - Yes" when the participant has seen a physician during the last two weeks.

! Code "0 - No" when the participant has not seen a physician during the last two weeks.

4 **References**

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- 2) Systolic Hypertension in the Elderly Program (SHEP) Manual of Operations. Revised April 17, 1985.
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- 4) American Thoracic Society ATS-DLD-78 Standard Respiratory Questionnaire (Am Rev

Respir Dis 1978; 118 (Part 2): 7-53).

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ORAL GLUCOSE TOLERANCE TEST

5 Background and Rationale

The oral glucose tolerance test (OGTT) is the standard test to determine whether diabetes or a milder abnormality of glucose tolerance is present. In middle age diabetes is associated with increased cardiovascular disease and is an especially strong risk factor for heart disease in women.

Performing the OGTT in CHS will help to answer several questions. Glucose tolerance decreases with age; some investigators believe that abnormal glucose tolerance is a significant risk factor for heart disease in the elderly while others believe that mild abnormalities are benign and constitute a part of normal aging.

A glucose tolerance test is necessary to document abnormalities in the elderly. Between 50 and 80% of elderly persons with abnormal glucose tolerance are asymptomatic. In population surveys, approximately 50% of diabetics and almost all subjects with impaired glucose tolerance will not have been diagnosed. Although the fasting glucose measurement will identify some diabetics, this measurement alone will miss approximately 50% of subjects with abnormal glucose tolerance.

Although the glucose tolerance test could be performed safely in all CHS participants, data obtained from diabetics taking insulin or oral hypoglycemic drugs would be difficult to interpret, and thus will not be done.

6 Definitions

6.1 Oral glucose tolerance test (OGTT): A standardized test for the diagnosis of diabetes and other abnormalities of glucose tolerance. It has several forms. The simplest, or survey OGTT recommended by the World Health Organization for diabetic screening, consists of a fasting blood sample, consumption of a standard glucose containing (75 g) drink, and obtaining a second blood sample two hours after the start of consuming the drink.

6.2 Fasting: Abstinence from all food and drink (except water and prescription medications) for a minimum of 12 hours prior to clinic visit.

6.3 Hypoglycemic medication: Medications that lower blood sugar. There are two classes, insulin, which is administered by injection, and oral hypoglycemics.

6.4 Diabetes: A metabolic disease characterized by abnormally high blood sugar and an increased risk of several chronic complications including heart and vascular disease, eye, and kidney disease. Many with this disease are asymptomatic but remain at increased risk of complications.

6.5 Impaired glucose tolerance: Abnormal glucose tolerance level between normal and diabetes. These persons appear to have an increased risk of cardiovascular disease, but little or no increased risk of eye and kidney disease.

7 Methods

O All participants are asked to come to the clinic in the morning after a 12-hour fast.

O All CHS participants except diabetics treated with insulin or oral hypoglycemics will have the glucose tolerance test.

O When a participant comes to the clinic in a non-fasting state, the initial blood draw is done, however the OGTT is not done. These participants will be rescheduled and another attempt made to obtain a fasting blood sample and

OGTT.

- O After the initial blood draw, the participant leaves the phlebotomy station and goes directly to the station where the glucose drink is administered.

NOTE: Clinic staff should reassure participants that the OGTT is safe and has few, if any, side effects. There are many misconceptions regarding the OGTT. Until a few years ago, larger doses of glucose were commonly administered and some patients complained about the fluid volume and/or subsequent GI distress. During the last ten years, a lower dose of glucose has greatly reduced this problem. In a study performed by the National Institute of Aging, only 0.3% (3 per thousand) subjects complained of side effects, all of which were mild and transient. No significant problems were encountered in those over 75 years of age. Because some participants may have heard that this test is uncomfortable, it is important to reassure them that this test should cause them no discomfort. If participants complain of any problems during the test, they should be recorded in the participant folder.

- O All eligible participants receive a standard 75 gram glucose load as a flavored drink (approximately 7 ounces). This is consumed in its entirety in 10 minutes or less.
- O Timing for the test begins as soon as the participant starts to drink the glucose solution.
- O If the full contents of the test drink are not consumed a note should be made in the participant folder.
- O If the participant drinks less than half of the test drink the test is canceled and no 2 hour blood draw performed.
- ! Two hours after the start of the test, the two hour blood sample is obtained for measurement of glucose and insulin.
- O The blood sample should be drawn as close to the two hour time as possible.
- O If blood cannot be obtained within 10 minutes of the scheduled time, the sample should still be drawn.
- O Record the time the sample was obtained on the OGTT Form and when appropriate record a reason for any delay.
- O Every scheduling effort should be made to allow participants to go to the phlebotomy station for the 2 hour blood sample. In a complex study such as CHS, it is inevitable that some participants will be having other parts of the examination. Adjustments will be necessary as staff gains expertise at each Field Center.

- O If the 2 hour blood sample is due and the participant cannot come to the phlebotomy room, the phlebotomy technician, if possible, should go to the participant to obtain this sample. A note should be made whenever this is necessary. Clinic staff must make this decision taking into account the safety and comfort of the participants.

7.1 Guidelines for examination of diabetic volunteers

7.1.1 Determination of diabetic status:

- O Diabetic status is determined during the Home Interview and the following instructions given to the participants:
 - ! Diet-controlled diabetics are instructed to fast overnight.
 - ! Diabetics taking hypoglycemic medications are instructed to fast overnight (unless a bedtime snack was prescribed by their physician) and to come to the clinic without taking their morning oral hypoglycemic medication. The morning medication dose should be brought to the clinic.
 - ! Insulin-dependent diabetics are instructed to fast overnight (unless a bedtime snack was prescribed by their physician) and to come to the clinic without taking their morning insulin. The morning insulin dose should be brought to the clinic.
- O The presence of previously diagnosed diabetes and whether hypoglycemic medications (oral sulfonylureas or injected insulin) are taken will be verified during the Reception Station Interview.

7.1.2 Fasting Blood Sugar and Oral Glucose Tolerance Test

- O All participants:
 - ! Fasting blood samples are drawn promptly after arrival at the clinic.
 - ! Diabetic participants not taking hypoglycemic medications will be treated exactly like all other CHS participants.
- O Insulin-dependent and Oral Hypoglycemic-dependent participants:
 - ! The oral glucose tolerance test is not done on insulin-dependent or oral hypoglycemic-dependent diabetics.
 - ! Fasting blood samples should be drawn promptly on arrival at the clinic.

- ! All known diabetics taking insulin or oral hypoglycemic medications should be scheduled for examination before 9 a.m.
- ! Immediately following the fasting blood draw, the participant takes his/her usual diabetic medication and has a snack provided by the Field Center. This snack must be provided promptly (within 10 minutes) after the diabetic medication is taken.

7.2 Potential problems in diabetic CHS volunteers

An additional consideration is the possibility that diabetic participants will develop low blood sugar or an "insulin reaction". The best protection against this is to be certain that each diabetic eats breakfast after his/her fasting blood is drawn and medications taken. However, in a large study, a few hypoglycemic reactions may still occur. If recognized promptly by clinic staff, they should be mild and easily treated with orange juice or a similar sugar containing beverage. An additional problem, marked hyperglycemia or uncontrolled diabetes, should be very rare in participants examined by CHS.

7.3 Emergencies associated with diabetes

Hypoglycemia

Hypoglycemia, or an abnormally low blood glucose level, occurs when there is an imbalance between the dose of hypoglycemic medications and the diabetic patient's food intake and activity level. Classic symptoms include anxiety, tremor, palpitations, sweating, faintness, and hunger. If untreated, a further decrease in blood glucose may lead to confusion followed by loss of consciousness. Prolonged hypoglycemia may cause permanent brain damage or precipitate angina pectoris or seizures.

It is important to remember that symptoms of hypoglycemia are variable and may be partially masked in elderly participants.

If a diabetic displays any of these symptoms and is able to take food orally, orange juice containing additional sugar should be given immediately. This should be sufficient to treat most hypoglycemic reactions. If a diabetic loses consciousness, hypoglycemia should be presumed until ruled out. Severe hypoglycemic reactions are a medical emergency and should be treated promptly with intramuscular glucagon or intravenous glucose. Clinics should have staff trained to administer one of these emergency therapies. If a comatose participant does not respond promptly, he/she should be transported immediately to an emergency care facility. If a severe hypoglycemic reaction occurs, the diabetic should be evaluated by medical staff prior to returning home.

Hyperglycemia

Hyperglycemia, an abnormally high blood glucose level, occurs when diabetes is not adequately controlled. In general, unusually high glucose levels will be reported to the

Field Center from the Central Blood Analysis Laboratory and dealt with according to notification protocols. It is unlikely but possible that a diabetic will present for examination with very poor diabetic control. Any diabetic participant complaining of persistent thirst, or who appears visibly short of breath or confused, should be referred for further evaluation since these could be indicative of more severe complications of diabetes requiring prompt medical treatment.