

YEAR 5 CLINIC VISIT

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YEAR 5 CLINIC VISIT

1. Overview of measurements

All Health ABC participants who attend the Year 5 clinic visit will have the following measurements unless specifically excluded according to criteria described in each chapter:

- In-clinic interview
- Medication inventory update
- Weight
- Blood pressure
- Bone density (hip and whole body)
- Heel ultrasound
- Assessment of arthritis; knee and hip pain
- Knee crepitus
- 20-meter walk
- Isokinetic ankle strength
- Pulmonary function test
- Teng mini-mental state
- Digit symbol substitution
- Executive Control Function (CLOX 1)
- Hearing

Subgroups of participants may have the following measurements:

- Cognitive vitality substudy measurements (administered to participants who were recruited for the cognitive vitality substudy during Year 3 of Health ABC). The cognitive vitality substudy includes of the Buschke selective reminding test, and various assessments of speed and reaction time.
- Flu substudy measurements (interview, grip strength, chair stands, standing balance, 4-meter walk, isometric strength, phlebotomy)
- Year 4 weight change substudy follow up measurements (interview and phlebotomy)
- Knee x-ray (participants with new knee pain or follow-up subgroup)
- Knee MRI (follow-up subgroup)

After the completion of each component of the Health ABC Year 5 clinic visit, the Procedure Checklist should be completed (see Appendix 1). Consent for release of results to physicians should also be indicated on the cover sheet of the Health ABC Year 5 Clinic Visit Workbook (Memphis only).

Scripts in protocols and worksheets

It is very important that examiners read the Health ABC operations manual. Scripts are included in the operations manual in order to standardize the administration of the many tests given to participants in the study. These scripts clearly identify key points that are important to convey to the participant. A number of worksheets also include script. Examiners are encouraged to learn the standardized script that appears in the protocols and/or worksheets, but they are free to modify the script in order for the presentation to sound natural, as long the same information is conveyed to the participants and is presented in the same order as the standardized script. There are exceptions to this rule, however. If a protocol indicates that you should use an exact script do not deviate from the required wording.

2. Working with older participants

Participants in our research studies are NOT patients; they are very valued volunteers who deserve to interact with study staff who are always at their best. The participants are people who are willing, for very little in return, to contribute their time, energy, and honesty about their situations in the hope of making a difference. We need to do everything we can to make their time with us an enjoyable experience. In order for Health ABC to be successful, we need participants to agree to return for several more years after their Year 5 visit. If they do not feel that they were treated with respect, we may lose them for follow-up. Time spent in making their visit as pleasant as possible is time well spent.

Research participants are free to refuse to have any test completed and/or to answer any questions that we ask. Because people who volunteer for studies tend to be generous people, refusals rarely happen. When they do occur, it is often because they do not understand what is being asked of them or why it is being requested. Take the time to explain. However, if they still refuse, respect this decision as their absolute right and move to another activity or question.

It is imperative that research participants are always treated with respect. This involves, but is not limited to, providing the necessary information to prepare them for their visit, greeting them warmly as they arrive in clinic, thanking them for their participation before the exams are started, answering any questions that they may have, explaining available test results at the end of the visit, thanking them again for their time and interest at the end of the visit, and not wasting their time by making them wait for long periods unnecessarily.

Dealing successfully with older research participants requires that we be sensitive to their potential needs and concerns. These needs may be related to ambulation difficulties, hearing and sight difficulties, discomforts associated with completing the clinic visit (e.g., fatigue due to their health status combined with a long visit, etc.), competing personal difficulties (e.g., depression, an ill spouse, etc.), and the experience of being a research participant.

The information we collect as research data may identify a new medical problem that may need to be brought to the attention of a participant's primary care physician for follow-up. We, as study staff, do not provide diagnosis or treatment. However, when participant consent has been obtained, we may need to notify appropriate parties (i.e., physicians, participants themselves, proxies, etc.) of a new abnormal finding. This should be accomplished by the clinic coordinator(s) after discussing the finding with the medical director/investigator.

Occasionally participants are wary of finding out that there is something "wrong" with them that they would rather not know. Tread lightly! Participants have a right to have this information remain unreported to them or to their physicians, family members, etc. Again, often their refusal is due to a lack of understanding and/or information. Take the time to discuss their fears. Contact the clinic coordinator to assist in the discussion as needed. However, participants do have the right to refuse to have information made known to themselves and/or others.

Keep in mind that, for the most part, participants who report feeling "fine" are "fine." Relax and enjoy your time with our Health ABC participants!

For Clinic Coordinators and Investigators:

We have an obligation to communicate with our participants and/or their physicians when appropriate. Participants deserve to receive their test results in a timely fashion. These results should be reviewed by the clinic coordinator / investigators prior to being sent to the participant and/or their physician. There should be no surprises when a participant receives their results in the mail. When possible, the clinic coordinator should discuss any abnormal findings with participants BEFORE the results are sent in the mail. Coordinators need to be sure that test results are complete and accurate; and these results must be sent out as quickly as possible. The Participant Results Report serves as an important thank-you for time spent participating in each Health ABC examination.

3. Preparation for the Year 5 clinic visit

3.1 Participant preparation

Each participant who comes to the Health ABC clinic visit will have been told about the contents of the visit during the phone conversation to schedule the clinic visit. Reminder letters should be mailed approximately 7 to 10 days prior to the visit to emphasize the following:

- date and time of the Year 5 clinic visit
- that participants can take their usual medications and eat prior to coming in to the clinic (i.e., fasting is not required this year).
- that participants should wear comfortable clothing and footwear and not wear jewelry.

- if participants use glasses, that they bring both their reading glasses and any glasses that are used for longer distances.
- that participants who wear hearing aids should bring or wear them to the clinic.
- that participants bring in medications (prescription AND non-prescription and inhalers, if used) that were taken in the last two weeks only.

Ideally, reminder phone calls should be made the day before the clinic visit. Please see an example of a reminder letter in Appendix 2.

3.2 Year 5 clinic visit preparation

At the time of the Year 5 clinic visit, the following should be available for each participant:

- A Data from Prior Visits Report should be generated with information that will be needed for the Year 5 clinic visit (see Appendix 3)
- Your HABC Participant Contact Information report from the Access system with the participant's contact information (address, phone number, proxy, next of kin, power of attorney, etc.).
- A Year 5 Questionnaire labeled with the participant's name, acrostic, and Health ABC enrollment ID number
- A Year 5 Clinic Visit Workbook labeled with the participant's name, acrostic, and Health ABC enrollment ID number
- A Year 5 Participant Results Report to give the participant at the end of their clinic visit
- The participant's chart. Field centers should also keep "progress notes" in the participant's chart. Progress notes may be used to record examiner comments and questions, and to document protocol problems and their resolution. Each entry should be dated and signed by the examiner recording the note.

The following should be available for sub-sets of Health ABC participants:

- Year 5 Cognitive Vitality Substudy Workbook
- Flu Substudy Eligibility Assessment form

- Flu Substudy Workbook
- Year 4 Weight Change Substudy Follow-up Workbook
- Knee X-ray Tracking form for participants who are eligible for knee x-rays because they are included in the knee x-ray follow-up subgroup (see Data from Prior Visits Report) or they have new knee pain and have not yet had a knee x-ray.
- Knee MRI Tracking form for participants who are eligible for knee MRIs because they are included in the knee MRI follow-up subgroup. These participants are identified on the Data from Prior Visits Report.

Table 1 [below] lists all the forms that are completed during the Year 5 Clinic Visit. Note that the Flu Substudy Workbooks, Cognitive Vitality Substudy Workbooks, and Year 4 Weight Change Substudy Follow-up Workbooks are completed only for sub-samples of participants; the Knee X-ray Tracking form is completed only for participants who are eligible for a knee x-ray, and the Knee MRI Tracking form is completed only for participants who are eligible for knee MRI.

Table 1	
<u>Health ABC Year 5 Clinic Visit Forms</u>	
Year 5 Questionnaire	Year 5 Clinic Visit Workbook (cont.)
Year 5 Clinic Visit Workbook:	CLOX 1
Year 5 Clinic Visit Procedure Checklist	Hearing
Medication inventory update	Isokinetic ankle strength
Weight	Pulmonary function test
Blood Pressure	Teng mini-mental state
Bone density (DXA) scan	Digit symbol substitution
Ultrasound	
Assessment of arthritis (knee and hip pain)	Year 5 Cognitive Vitality Substudy Workbook
Knee crepitus	Knee X-ray Tracking Form
20-meter walk	Knee MRI Tracking Form
	Flu Substudy Eligibility Assessment
	Flu Substudy Workbook
	Year 4 Weight Change Substudy Follow-up Workbook

4. Clinic flow and measurements

4.1 Overview of clinic flow

Every effort should be made to keep the visit as short as possible. One way to save time is to have the participant put on their gown after their blood pressure exams so that they don't have to put on the gown and then take it off. Another time-saving idea is to do tests consecutively that require that participants not be wearing shoes (DXA, weight, ultrasound). Also, if the Consent Form is sent out ahead of time, many participants will be ready to sign it right away when they arrive at the field center, instead of taking the time to read it during their clinic visit. The following guidelines for the order of specific measurements are divided into mandatory, which must be followed, and preferable, which are highly recommended but may be modified without jeopardizing the standardization of the measurements:

Mandatory

Blood pressure before Isokinetic Ankle Strength (Kin-Com)
and Pulmonary Function Test

Medication inventory (pages 2 through 6 in the Year 5 Clinic Visit Workbook)
before Pulmonary Function Test

Year 5 Clinic Visit Workbook Assessment of Knee Pain
(Questions 2, 3, 4, and 5 on pages 15, 16, and 17)

before Knee X-ray Eligibility (page 19 in Year 5 Clinic Visit Workbook)

Year 5 Questionnaire (Question #6, page 2) before Flu Substudy Eligibility
Assessment

Flu Substudy Eligibility Assessment before Flu Substudy Workbook for first flu
substudy visit.

Preferable:

Group together weight, bone density scan, and ultrasound
Cognitive Vitality Substudy at end of clinic visit

4.1.1 Year 5 in-clinic follow-up interview

The Year 5 Questionnaire will be administered during the Year 5 clinic visit. The questionnaire does not have to be completed all at once, and can be administered in sections during the course of the clinic visit, with special care that each section be completed. Also, there is a section of the questionnaire that must be administered before the flu substudy eligibility assessment and workbook can be administered.

4.1.2 Medication inventory

Prescription and non-prescription medications used by participants in the two weeks prior to their Year 5 clinic visit will be recorded on the Medication Inventory Form (MIF) in the Year 5 Clinic Visit Workbook. Review the listing on the Data from Prior Visits Report for start dates and dosages of medications that the participant was taking at their Year 3 clinic visit. Determine if the participant is still taking the medications listed on the Data from Prior Visits Report. If these medications were taken in the past two weeks, they have to be re-written on the Year 5 Medication Inventory form, but time will be saved if you review the medications that are listed on this form. Also, add any new medications that the participant has used in the past two weeks.

See Chapter 2C for detailed procedures.

4.1.3 Weight

One of the most important measurements that is done for Health ABC is the weight measurement. The measurement of weight comes early in the exam and offers a good opportunity to answer questions and promote goodwill towards the study.

See Chapter 2B for detailed procedures.

4.1.4 Blood pressure

Sitting blood pressure measurements will be obtained. The blood pressure will be used for the isokinetic ankle strength (Kin-Com) and pulmonary function test; individuals with extremely high blood pressure will be excluded from isokinetic strength and pulmonary function testing and referred for medical care according to the protocol for referrals.

See Chapter 2D for detailed procedures.

4.1.5 Bone density (DXA)

Bone mineral density of the hip and whole body will be performed using the Hologic QDR 4500 instrument. Body composition measurements are obtained during the whole body scan. BMD of the hip should be performed on the same side that was scanned at baseline, unless the participant has had a hip replacement on that side.

See Chapter 2E for detailed procedures.

4.1.6 Ultrasound

Quantitative ultrasound (QUS) may be a useful measure of both the quality and quantity of bone. In Health ABC we will be measuring QUS with the Hologic Sahara.

See Chapter 2F for detailed procedures.

4.1.7 Assessment of arthritis, knee and hip pain, and knee crepitus

During the Year 5 clinic visit participants will be asked questions regarding knee and hip pain (see pages 15 through 18 in the Year 5 Clinic Visit Workbook). Also, there will be a knee crepitus evaluation.

See Chapter 2G for detailed procedures.

4.1.8 20-meter walk

This is a modification of the short walk test used in many epidemiological and clinical studies. The test is divided into two parts.

- the time to walk 20 meters at the participant's usual pace along with the number of steps, and
- the time to walk 20 meters as fast as the participant can, along with the number of steps

See Chapter 2H for detailed procedures.

4.1.9 Isokinetic Ankle Strength (Kin-Com)

A Kin-Com isokinetic dynamometer will be used to evaluate the concentric strength of ankle dorsi and plantar flexors.

See Chapter 2I for detailed procedures.

4.1.10 Pulmonary function test

Pulmonary function tests on each participant will include:

- Maximum inspiratory pressure (MIP)
- Forced expiratory spirometry
- Slow vital capacity (only if a participant cannot perform the forced maneuver)

You will need the participant's height to do the PFT measurement. The participant's Year 4 height should be on the Data from Prior Visits Report. If the participant's Year 4 height was not measured, measure the participant's height during their Year 5 clinic visit. Do not use the height from baseline.

See Chapter 2K for detailed procedures.

4.1.11 Teng Mini-Mental State

The MMSE (Mini-Mental State Examination) is a widely used test of cognitive function among the elderly. It includes tests of orientation, registration, attention, calculation, recall, and visual-spatial skills. The Teng Mini-Mental is an expanded 100 point version of the original Folstein MMSE designed to increase the standardization, sensitivity, and specificity of the test as a screen for dementia. This form of the test was designed to sample a broader variety of cognitive functions, cover a wider range of difficulty levels, and enhance the reliability and validity of the scores.

See Chapter 2N for detailed procedures.

4.1.12 Digit symbol substitution

The Digit Symbol Substitution Test (DSST) may be a more sensitive measure of dementia than the MMSE. The DSST requires response speed, sustained attention, visual spatial skills and set shifting. It is part of the Wechsler Adult Intelligence Scale, one of the most widely used measures of intelligence.

The DSST requires that the participant fill in a series of symbols correctly coded within 90 seconds. In this test the higher the score the better the person's performance.

See Chapter 2M for detailed procedures.

4.1.13 Executive Control Function - CLOX 1

Executive control function will be measured using the CLOX 1, a clock-drawing test. Impairment in executive control function is thought to contribute to loss of independence through interference with the ability to initiate, direct, plan, and execute complex goal-directed activities, such as preparing meals, following a medication regimen, etc.

See Chapter 2L for detailed procedures.

4.1.14 Hearing

Hearing impairment increases dramatically in prevalence and severity in old age, especially past age 80. It is the third most prevalent common condition in community dwelling older adults, and is associated with other common comorbidities, especially dementia and depression. The lowest level (hearing threshold level) that participants can hear tones of different frequencies (pitch) will be measured and plotted on a graph (audiogram).

See Chapter 2J for detailed procedures.

4.2 Substudies

4.2.1 Knee Osteoarthritis (OA) Assessment – Knee x-rays and MRIs

To determine knee x-ray and/or MRI eligibility, follow the instructions on the Knee X-ray Eligibility Assessment form (page 19 in the Year 5 Clinic Visit Workbook). For those participants who will be having a knee x-ray and/or knee MRI, the information in the header of the Knee X-ray Tracking form and the Knee MRI Tracking form should be completed before the participant goes to the X-ray or MRI facility. The form should accompany the participant to the facility. The accuracy of participant identifiers on forms and images is extremely important.

Repeat knee x-rays

The Year 5 Repeat Knee X-ray Parameter form (attached to the Data from Prior Visits Report) that lists the participant's Health ABC enrollment ID number, name, and acrostic and that includes information regarding previous knee x-ray beam angles and mAs settings should accompany the Knee X-ray Tracking form of those participants who will be having a follow-up knee x-ray.

See Chapter 2Q for detailed procedures.

Repeat knee MRIs:

In addition to filling out the header on the Knee MRI Tracking form, the examiner should refer to the Data from Prior Visits Report to see which knee(s) should be scanned, and check the appropriate box(es) on Question #13 (page 3) of the Knee MRI Tracking Form: "Scan Right knee," and/or "Scan Left knee." The technician should refer to Question #13 to determine which knee(s) to image.

See Chapter 2R for detailed procedures.

4.2.2 Flu Substudy

In order to determine whether or not a participant will be eligible for the flu substudy, Question #6 on page 2 of the Year 5 Questionnaire must be asked: “Since we last spoke to you about 6 months ago, have you had a cold or flu that was bad enough to keep you in bed for all or most of the day?” If the participant answers “Yes” and had a temperature of 100 degrees or higher, they may be eligible to be part of the flu substudy, and the Flu Substudy Eligibility Assessment form should be completed.

A participant who was enrolled in the flu substudy previously may be re-enrolled in the flu substudy if they were first enrolled 12 or more months before the date of re-enrollment. Check the Data from Prior Visits Report to see if the participant was part of the flu substudy and, if so, what their enrollment date was. If their enrollment date was less than 12 months ago, the participant is not currently eligible for the flu substudy, but if it was more than 12 months ago, they are eligible to be part of the flu substudy again.

Please note that participants are recruited for the substudy not just during their Year 5 clinic visit, but during their Semi-annual Telephone Contact visit as well. Therefore, some participants may be coming in to the clinic for a special flu substudy visit, and will be coming back to the clinic for their yearly clinic visit at a later date. The flu substudy also includes a follow-up visit that may occur during the Year 5 clinic visit or as a separate visit.

See Chapter 2P for detailed procedures.

4.2.3 Cognitive Vitality Substudy

For Year 5, the study population will consist of the subset of Health ABC participants who participated in the Cognitive Vitality Substudy in Year 3. Participation constitutes completion of any of the cognitive tests (e.g., SRT, boxes, digit copying, pattern comparison, letter comparison, or reaction time tests) administered in Year 3. Look on the Data from Prior Visits Report to determine whether or not the participant should be administered the cognitive vitality substudy tests.

See Chapter 2O for detailed procedures.

4.3 Procedure checklist and exit interview

At the end of the Year 5 Clinic Visit, an exit interview should be performed to:

- Thank the participant. Be sure the participant knows how much we appreciate their participation.
- Answer questions. Some participants may have questions about various examinations.
- Make sure the Year 5 Clinic Visit Workbook Procedure Checklist is completed; ie., the header information including the Health ABC Enrollment ID #; time of arrival; time of departure; whether the visit included scheduling a knee x-ray or knee MRI; whether the Cognitive Vitality Substudy or Flu Substudy Workbook was completed; and permission to send test results to the physician (see Appendix 1). Confirm that all exams and measurements were completed. Review the Year 5 Clinic Visit Workbook and complete the Procedure Checklist appropriately. Record on the checklist whether or not a test was completed, was partially completed, whether or not the participant refused a test, or whether the test was not done for some other reason.
- Provide selected results (Appendix 4). Participants will be given the following results:
 - ⇒ Blood pressure. Each participant will be given current guidelines for follow-up and evaluation based on the blood pressure recorded.
 - ⇒ Weight. Weight in pounds should be provided.
 - ⇒ Hearing. Each participant will see their results mapped on a graph that shows their hearing thresholds compared to average hearing thresholds of other people in a similar age range.
 - ⇒ Pulmonary Function Test. Spirometry results will be given to each participant. These results include the percent predicted FVC, the percent predicted FEV1 and the ratio between the FEV1 and FVC. A brief explanation of what these values mean and what ranges are considered to be normal will also be included in the report.
 - ⇒ BMD and body composition. DXA results from the total hip should be provided as this site is the most reproducible and is used clinically. The participants BMD will be plotted by the DXA technician on a sex and race-specific normative curve. The participant will receive a body composition

results report that includes their percent body fat and where their results fit in the range of Health ABC participant results.

- Summarize future contact with the study both for scheduled visits and endpoints. Participants should be reminded to immediately contact the clinic for any of the following events:
 - ⇒ Hospitalization. Any overnight stay in an acute care facility.
 - ⇒ Surgery. Any surgery requiring regional (e.g., spinal) or generalized anesthesia. This includes same-day surgery that does not result in an overnight hospitalization.
 - ⇒ Fracture. Any broken bone, including minor fractures of the toes, fingers, etc.

Suggested script: “It is very important to the study for us to know as soon as possible about changes in your health. Between study visits, we ask that you call the clinic at this number (xxx) xxx-xxxx, if you are hospitalized overnight, have surgery, or break any bones.”

4.4 Incomplete Visits

Occasionally, a participant may not complete their entire clinic visit. They may agree to come in at a later date to have the exams that they missed during their first visit. It is important to minimize the amount of time between the first and the second visit. It is not necessary to reweigh the participants who come in for a second clinic visit. Use the weight that is recorded on page 2 of the Year 5 Clinic Visit Workbook for the DXA exam.

Very rarely, a measurement is not taken. Whenever a measurement is not taken, write the reason in the Comments section of the Year 5 Clinic Visit Procedure Checklist, and include a note in the progress notes in the participant's chart explaining why the measurement was not taken.

5. Alerts and Notifications

At the clinic visit, participants will receive a report that includes weight, blood pressure, PFT, hearing, and DXA results (see Appendix 4). Table 2 lists measures that have alert values; Appendices 7 and 8 contain examples of alert letters to physicians.

Table 2**Health ABC Tests: Alert Values****Defined Values**

Blood Pressure
 Bone Density
 Pulmonary Function
 (spirometry)

Examiner Discretion

Weight loss $\geq 10\%$
 Teng Mini-mental State

5.1.1 Blood Pressure

Immediate alert: ≥ 210 SBP or ≥ 120 DBP, refer to source of care immediately after discussion with the clinic physician.

Below are ranges of blood pressure measurements that require various schedules for referral to sources of care and ranges that are considered to be normal.

180-209 SBP or 110-119 DBP, refer to source of care within 1 week
 160-179 SBP or 100-109 DBP, refer to source of care within 1 month
 140-159 SBP or 90-99 DBP, confirm within two months
 130-139 SBP or 85-89 DBP, high normal, no referral required
 < 130 SBP or < 85 DBP, normal, no referral required

Blood pressure measurements will be given to the participant at the time of the clinic visit. A printed form with the above referral information and levels, with blanks for recording the participant's values will be provided (see Appendix 4).

5.1.2 Bone density (DXA)

The alert for DXA is loss of bone at a greater rate than 3% a year since baseline. (See Appendix 6 for alert letter to participant and Appendix 7 for the alert letter to physician to be sent after confirmation of excess bone loss from the DXA Reading Center [see Appendix 5 - Excessive Bone Loss Form].)

5.1.3 Pulmonary function test (spirometry)

The alert value is an FEV1 < 1.0 liter or < 40% of predicted (whichever is the smaller number (See Appendix 4).

5.1.4 Weight change

Participants with weight loss of $\geq 10\%$ that appears to be unexplained will have the weight change brought to the attention of their physician with the participant's permission (see Appendix 8).

5.1.5 Teng mini-mental state

Although there are no alert values for this test, we know that a score of 80 or less is roughly comparable to a score of 24 on the 0-30 scale and is used as a screening cut point for cognitive impairment. This is a screening test that varies with age and education. Additional clinical evaluation is needed for diagnosis. The field center physician or designee should look at the MMSE score compared to baseline and in the context of what else is known about the person, discuss the results with the participant on an individual basis. This would include sending the results to their doctor with permission.

6. Clinic Safety

6.1 Background and Rationale

All life threatening emergencies that occur at the Health ABC clinic, such as acute myocardial infarction, should be referred for immediate evaluation at an acute care facility, with emergency measures taken in the clinic before departure. Minor emergencies, such as hypotension or fainting, receive treatment in the clinic. Although most emergencies are of even less severe nature, Health ABC Field Center Clinics are prepared for both types.

6.2 Major Emergencies

When a serious life-threatening event occurs in the clinic setting, the primary concern of the clinic staff is to implement pre-established procedures to get the participant to the nearest medical facility. It is imperative that local emergency measures be activated; in most cases, this requires calling 911. Do not take the participant to the emergency room. Let the paramedics do that. At every clinic session a physician, physician assistant, or registered nurse with certification in basic life support is on duty and physically present. Needed life support procedures should be continued until emergency care arrives or the participant is transported to a hospital.

Each Health ABC clinic has specific emergency procedures which define:

1. Who is in charge during the emergency
2. Who administers treatments
3. Who is notified
4. What action clinic staff takes
5. Which reports are filed

Each clinic has, in addition to trained personnel and emergency equipment, posted in a conspicuous place, such as the reception area, the following:

- phone number of police station
- phone number of fire stations
- phone number of ambulance services

} **CALL 911 !**

In each participant's folder, the name and phone number of their physician or usual source of health care is available on a standard Health ABC form. The home and work telephone number of the next-of-kin are also listed.

All medical emergency situations should be coordinated by a physician when present in the clinic. In the physical absence of the latter, this role should be assumed by the charge nurse or senior physician assistant. When not physically present in clinic, they are within immediate reach by phone or paging system and within a short distance to the clinic. The physician duty roster is posted with the clinic secretaries and in the office of the head nurse and/or senior physician assistant so that the name of the responsible physician is readily accessible. However, in no case should emergency referral and/or care be deferred while staff is attempting to locate a clinic doctor. All personnel should be trained to carry out their specific responsibility during an emergency. Retraining is conducted at least yearly, inclusive of any emergency drill.

All major emergencies should be documented, identifying the type of emergency and action taken. This report should be completed by the clinic coordinator and co-signed by a clinic physician and the Principal Investigator. These reports should be maintained in a central file at each field center and a copy of the report should be kept in the participant's chart.

6.3 Minor Emergencies

The most common minor emergency is simple syncope (fainting) and near syncope.

In any situation in which syncope is likely, staff should verify that the participant does not look or feel faint. When the participant looks faint or feels faint the following steps should be implemented:

1. Have the person remain in the chair and sit with their head between their knees or lie down.
2. Crush an ampule of smelling salts and wave under the participant's nose for a few seconds. DO NOT place ampule directly under the nose.
3. Provide the participant with a basin and a towel when they feel nauseous.
4. Check blood pressure and pulse.
5. Have the participant stay in the chair until they feel better and their color returns. Re-check blood pressure and pulse.

If the participant continues to feel sick, recline the chair, place a cold, wet towel on the back of the person's neck, and notify the clinic nurse coordinator. When a participant faints, they should be cautiously lowered to the supine position on the floor and one attendant immediately calls for an in-house physician or nurse to assist the participant. The remaining attendant raises the participant's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the participant is breathing. When life support measures are needed, the measures outlined in the above sections are followed.

6.4 Emergency Equipment

A basic first aid kit is maintained at each field center. The kit contains a reference guide of its contents, and is checked every 6 months and immediately after each use. At each Field Center, the study coordinator identifies the person responsible for this task.

6.5 Emergency Plans in Case of Fire

1. Notify the emergency management system (911) to report the fire.

2. Close all windows and doors.
3. Escort all participants to the nearest fire exit and assemble a safe distance from the building.
4. Alert the clinic coordinator and the building supervisor of the emergency situation.

APPENDIX 1 Year 5 Clinic Visit Workbook Procedure Checklist

Health ABC

HABC Enrollment ID #	Acrostic	Date Form Completed		Staff ID #
H [] [] [] [] [] []	[] [] [] [] [] []	[] / [] / 200[] []	[] [] [] []	[] [] [] []
		Month	Day	Year

YEAR 5 CLINIC VISIT WORKBOOK

Arrival Time: [] [] : [] [] Hours Minutes
 Departure Time: [] [] : [] [] Hours Minutes

YEAR 5 CLINIC VISIT PROCEDURE CHECKLIST

Measurement	Page #	Yes: Measurement fully completed	Yes: Measurement partially completed	No: Participant refused	No: Other reason/ Not applicable	Comments
1. Year 5 Questionnaire		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2. Medication inventory update	2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3. Weight	7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
4. Blood pressure	7	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
5. Bone density (DXA) scan	8	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
6. Ultrasound	11	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
7. Assessment of arthritis, knee, and hip pain	15	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
8. Knee crepitus	20	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
9. 20-meter walk	21	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
10. Isokinetic ankle strength	22	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
11. Pulmonary function test	26	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
12. Teng mini-mental state	29	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
13. Digit symbol substitution	35	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
14. CLOX 1	37	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
15. Hearing	38	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
16. Was the Cognitive Vitality Substudy Workbook completed?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
17. Was the Flu Substudy Workbook completed?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
18. Did participant agree to schedule a knee x-ray?		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	
19. Did participant agree to schedule a knee MRI?		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	

Memphis Only:

Would you like us to send a copy of your test results to your doctor? Yes No

Page Link # [] [] [] [] [] []



APPENDIX 2: Health ABC Year 5 Pre-Visit Instructions

Dear _____:

Your appointment for your Health ABC Year 5 Clinic Visit has been scheduled for: _____, _____ at _____ a.m. at XXXXXXXXXX, XXXXXXXXX (a map is enclosed). Parking is available in the garage attached to our clinic or van transportation will be provided as prearranged.

Please be sure to review these instructions for your upcoming clinic visit, since they are very important for the success of your tests:

- Read all enclosed materials.
- Take all your regular medications, as usual.
- Feel free to eat breakfast (or lunch) prior to your visit.
- Wear comfortable shoes for walking. It would be helpful if you wear a short sleeved shirt, since this will make taking your blood pressure easier. Do not wear pantyhose or girdles. You will be asked to change clothes for some tests.
- Do not wear jewelry to the clinic, if possible, since this may make it more difficult to do your bone scan.
- If you have glasses, bring both your reading glasses and any glasses that you use for longer distances.
- If you have a hearing aid, bring it with you.
- A plastic bag has been provided for the prescription AND non-prescription medications that you have taken in the last two weeks only. Include eye drops, shots, supplements, vitamins, pain medications, laxatives or bowel medicines, cold medications, cough medications, antacids or stomach medicines, and ointments or salves. Bring these with you to the clinic.
- If you regularly use an inhaler for a lung or respiratory condition, be sure to bring this with you to the clinic.

Thank you again for your very valuable help in this important research study! We look forward to seeing you again.

Please call XXX-XXXX if you have any questions about your visit.

FLU SUBSTUDY

1. Was the participant enrolled in the Flu Substudy in Year 4?
 Yes No Unknown

2. What was the date that the participant was enrolled in the Flu Substudy?
 [] [] / [] [] / [] [] [] ▶ If this date is more than 12 months ago,
Month Day Year please complete the Flu Substudy Eligibility
Assessment Form; i.e., the participant can be
enrolled in the flu substudy again, if they are
eligible.

3. Is the participant due for a Flu Substudy follow-up exam at the time of their
Year 5 visit?

COGNITIVE VITALITY SUBSTUDY

Is the participant part of the Cognitive Vitality Substudy?
 Yes No

EVENT FORM DATA

The following Event Forms have been entered to date for this participant:

Event Form Reference #	Type of Event	Date of Event
------------------------	---------------	---------------

FOR PARTICIPANTS WHO WILL HAVE A CORE HOME VISIT/
PROXY HOME VISIT IN YEAR 5**BLOOD PRESSURE**

Which arm was used for baseline (Year 1) blood pressure?

Right Left Don't know / No baseline measurement

ISOMETRIC CHAIR

1. Has participant ever had an isometric chair measurement?

Yes No

2. Which leg was tested during the most recent isometric chair measurement?

Right Left None recorded

3. **Examiner Note: use the same setup parameters as before:**

Seat Height: [] [] [] mm

Seat Depth: [] [] [] mm

4. Has participant ever had a Kin-Com exam? Yes No Unknown

5. Which leg was tested during the most recent Kin-Com exam?

Right Left None recorded

FOR PARTICIPANTS WHO WILL HAVE AN IN-CLINIC VISIT IN YEAR 5**BLOOD PRESSURE**

Which arm was used for baseline (Year 1) blood pressure?

Right Left Don't know / No baseline measurement

BONE DENSITY (DXA) SCAN

Which hip was scanned at baseline (Year 1)?

Right Left Don't know / No baseline measurement

ULTRASOUND (SAHARA)

Which heel was scanned at Year 2?

Right Left Don't know / None recorded

KNEE X-RAY ELIGIBILITY

1. Is the participant eligible for a follow-up knee x-ray?

Yes No Unknown

2. Did participant have knee symptoms that met eligibility criteria for knee X-ray in Year 2, Year 3 or Year 4?

Yes No Unknown

3. Did the participant have a knee x-ray in Year 2, 3, or 4?

Yes No Unknown

KNEE MRI ELIGIBILITY

1. Is the participant eligible for a follow-up knee MRI?
 Yes No
2. If Yes, which knee should be imaged?
 Right Left Both Right and Left

PULMONARY FUNCTION TEST

1. Participant's height at their Year 4 clinic visit:
 cm
2. Did participant have PFT alert at baseline?
 Yes No

WEIGHT CHANGE ALERT

1. Participant's weight at their Year 4 clinic visit:
 [] [] [] kg
2. Participant's weight at their Year 4 clinic visit (-) 10%:
 [] [] [] kg

YEAR 5 REPEAT KNEE X-RAY PARAMETERS

(Attach this form to the front of the Knee X-ray Tracking Form before sending the participant for the knee X-ray.)

Health ABC ID# _____

Participant Name _____

Acrostic _____

X-ray Technician Please Note: Use the first beam angle specified below. If a second angle is specified, obtain a second PA film using that angle:

First beam angle:

[][] degrees

Second beam angle:

[][] degrees

The following parameters were used on the first knee x-rays for this participant. These should serve as guidelines for setting up the current follow-up knee x-rays. However, if these parameters do not result in high quality x-rays, then other parameters should be tried to maximize x-ray quality.

mAs setting for the axial view of the right knee:

[][] mA

mAs setting for the axial view of the left knee:

[][] mA

MEDICATION INVENTORY

The following is a listing of prescription and non-prescription medications used by the participant in Year 3. Please confirm with the participant whether this information is still current and complete and update the MIF, being careful to determine whether medications listed below were used continuously or whether there is a new start date.

Medication Name	#Used	per D/W/M	PRN?	Reason for Use	
	Mo	Day	Yr Started	Form Code	Rx/Non-Rx

APPENDIX 4 Health ABC Examination Results
page 1 of 12



Year 5 Participant Results

Participant Name:

(Please Print)

Date of Year 5 Clinic Visit: ____ / ____ / ____
Month Day Year

Weight: ____ ____ pounds

Blood Pressure: ____ ____ / ____ ____ mm Hg

Normal:	Less than 130/85 mm Hg
High normal:	130-139/ 85-89 mm Hg
Hypertension:	140/90 mm Hg or higher

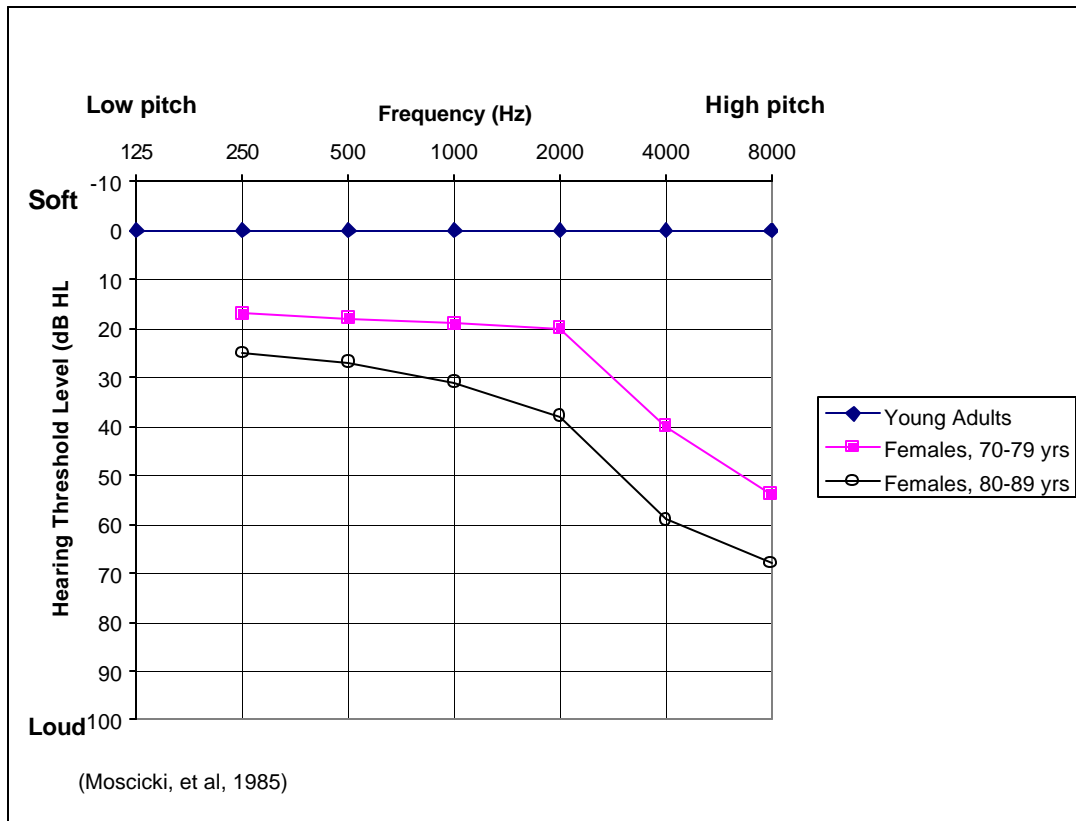
Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that you:

- Recheck blood pressure within 1 year Comments: _____
- Recheck blood pressure within 2 months _____
- See your doctor in 1 month _____
- See your doctor in 1 week _____
- See your doctor immediately _____

If you have any specific questions about your blood pressure, please talk with your doctor.

[Women]

HEARING TEST



The Audiogram

The graph above is called an audiogram. Audiograms are used to plot the **lowest level** (hearing threshold level) that people can hear different tones. Young adults have hearing thresholds around 0 decibels. Hearing thresholds for people with normal hearing are usually between -10 decibels and 20 decibels. Average conversational speech is around 50 to 60 decibels. As we get older we tend to lose hearing. We especially have trouble hearing high pitched sounds.

The audiogram shows the average hearing thresholds for young adults and for women between the ages of 70-79 and 80-89 years.

Understanding Your Hearing Results

If your hearing test results were not as good as the results of other people your age, or if you are finding it difficult to have a conversation, you may want to visit a hearing specialist (audiologist). Based on a complete hearing evaluation, the audiologist may refer you to a doctor or recommend a hearing aid or other hearing device.

[Women]

LUNG FUNCTION TEST

Lung Function Test	Your Value	Usual Normal Range
<p>FVC: total amount of air you blew out of your lungs</p>	<p>_____ % of Predicted</p>	<p>80% and greater</p>
<p>FEV1: FEV1 is the amount of air you were able to blow out in the first second)</p>	<p>_____ % of Predicted</p>	<p>80% and greater</p>
<p>FEV1/FVC: FEV1/FVC is the ratio of the other two volumes</p>	<p>_____</p>	<p>65% and greater</p>

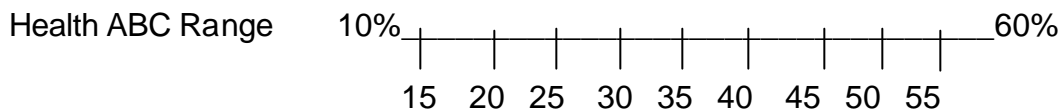
- The lung function test was not performed or lung function could not be determined accurately.
- Your values are within the normal range or above; your lung function is normal.
- Your values are below the usual range; your lung function is somewhat below normal. About 5% of healthy people have values just below the normal range.
- If either of your values is less than 50% of your predicted normal value, or if your FEV1/FVC ratio is less than 50%, your function is substantially reduced.

BODY COMPOSITION IN WOMEN

One of the goals of Health ABC is to determine how weight and body composition (fat and lean muscle mass) affect health as we get older. With age, our weight changes and this is often the result of an increase in body fat along with a decrease in lean mass. These changes in body fat and lean mass may lead to an increased risk for health problems and disability. For example, obesity (high percent body fat) may reduce life expectancy by increasing the risk of developing coronary artery disease, high blood pressure, Type II diabetes, certain types of cancer, and several other diseases including arthritis. Although less common, a person may have too little body fat. Since we need a certain amount of body fat (called essential fat) to maintain normal body functions, older men and women with too little fat may also be at risk for health problems.

The bone density test you had during your most recent Health ABC visit also allowed us to measure your percentage of body fat. It is important to measure percent fat in addition to weight alone since *it is the composition of the weight that may be important and not weight alone*. Your body fat percentage is marked below along with the range of body fat percentage in the Health ABC population. There is no exact level of percent body fat that is definitely associated with risk of health problems or disability among all older adults. As a participant in Health ABC, you are helping us to determine what percentage of body fat either maintains or improves health as we age or increases the risk for poor health or disability as we age.

Your Percent Body Fat: _____ %



[Women]

BONE MINERAL DENSITY - WOMEN

Thank you for your continued participation in the Health ABC study. Attached are the results from your bone density test from your Year 5 clinic visit. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this report is to help you and your doctor understand your bone density measurement.

What is a bone density measurement?

A bone density test measures how much calcium is contained in certain bones, such as the hip. In general, lower bone density and lower calcium means that the bone is weaker.

What do bone density measurements mean?

We all lose bone as we get older, but some people lose bone faster than others. Certain factors can reduce bone density, such as smoking, low calcium intake, lack of exercise, high alcohol intake, use of some medications, and some medical conditions.

Individuals with low bone density have weaker bones, and weaker bones are more likely to fracture during an accident (even a minor accident such as a fall). However, not all women and men with low bone density will have fractures and, occasionally, even those with high bone density will suffer a fracture.

What are my bone density results?

Your hip bone density value was compared to that of young women and is at the level checked below:

_____ Normal
_____ Low
_____ Osteoporosis

If your bone density is checked as "low" or "osteoporosis," we suggest that you discuss these results with your personal doctor, and we would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a local doctor who specializes in treating osteoporosis.

If you have questions regarding these results, please contact _____ at _____.

[Women]

Muscle strength and walking speed tests

We do not know yet what results are considered “normal” for these tests. You are helping us understand how body changes may cause new health problems and how to prevent disability as we get older. In future years, with your continued participation, we may be able to tell you how your test results compare with others.

Knee crepitus

Knee crepitus is when a clicking, popping, or grinding is felt when you put your hand over your knee while you move your leg forward and backward. Knee crepitus is common in people with osteoarthritis of the knee, but it also occurs in people who do not have knee osteoarthritis. If a person has both knee pain and crepitus, they may have knee osteoarthritis. It is not known what it means to have crepitus without knee pain.

Treatments for osteoarthritis include medications to reduce pain and inflammation (aspirin and nonsteroidal antiinflammatory drugs), exercise, and for knee osteoarthritis, in particular, weight control.

Ultrasound

We do not know yet what results are considered “normal” for the ultrasound test. Low ultrasound measurements may be an indication of poor bone quality, but the exact meaning is unclear.

Memory and reaction time tests

There are no “normal” values for many of these tests. By repeating these tests in future visits you will help us learn more about how memory and reaction time changes with age and in relation to lifestyle and changes in health.

We would like to thank you for your continued participation in the Health ABC study. These tests were done for research purposes only and were not intended to diagnose any health problems. However, we encourage you to share these results with your doctor. If you have any questions, please call the Health ABC clinic at:

() _____.



Year 5 Participant Results

Participant Name: _____
(Please Print)

Date of Year 5 Clinic Visit: ____ / ____ / ____
Month Day Year

Weight: _____ pounds

Blood Pressure: _____ / _____ mm Hg

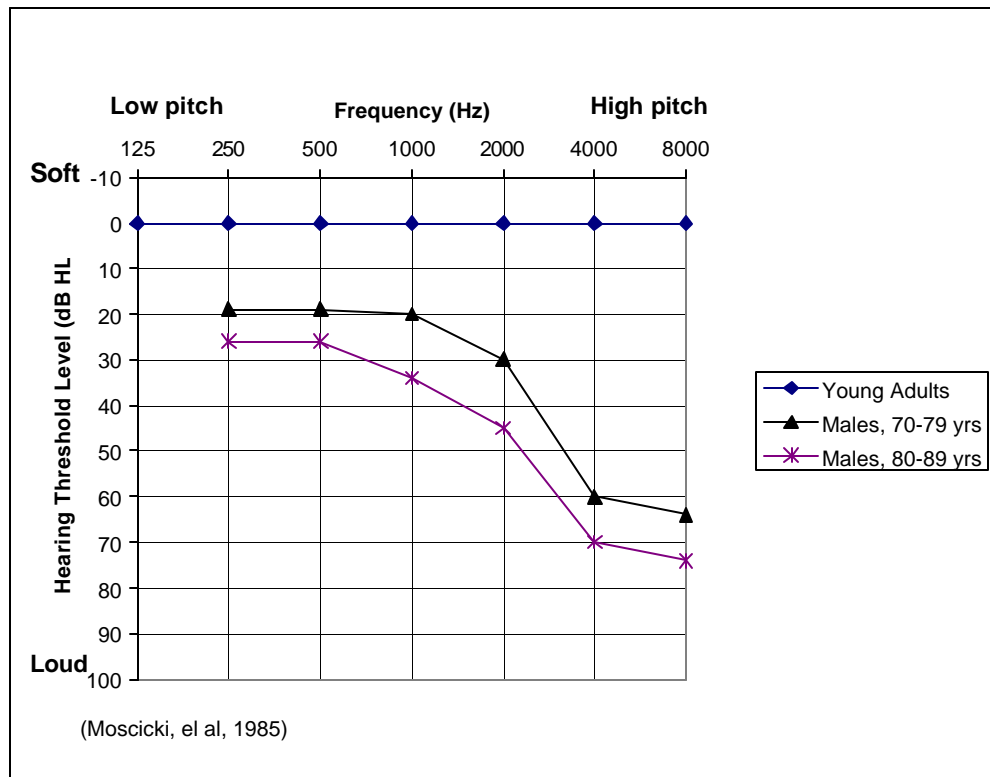
Normal:	Less than 130/85 mm Hg
High normal:	130-139/ 85-89 mm Hg
Hypertension:	140/90 mm Hg or higher

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that you:

- Recheck blood pressure within 1 year Comments: _____
- Recheck blood pressure within 2 months _____
- See your doctor in 1 month _____
- See your doctor in 1 week _____
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HEARING TEST



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The audiogram shows the average hearing thresholds for young adults and for men between the ages of 70-79 and 80-89 years.

Understanding Your Hearing Results

If your hearing test results were not as good as the results of other people your age, or if you are finding it difficult to have a conversation, you may want to visit a hearing specialist (audiologist). Based on a complete hearing evaluation, the audiologist may refer you to a doctor or recommend a hearing aid or other hearing device.

[Men]

LUNG FUNCTION TEST

Lung Function Test	Your Value	Usual Normal Range
FVC: total amount of air you blew out of your lungs	_____ % of Predicted	80% and greater
FEV1: FEV1 is the amount of air you were able to blow out in the first second)	_____ % of Predicted	80% and greater
FEV1/FVC: FEV1/FVC is the ratio of the other two volumes	_____	65% and greater

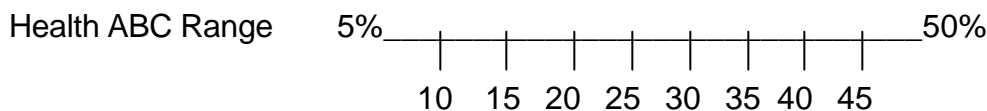
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- If either of your values is less than 50% of your predicted normal value, or if your FEV1/FVC ratio is less than 50%, your function is substantially reduced.

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Your Percent Body Fat: _____ %



[Men]

BONE MINERAL DENSITY

Thank you for your continued participation in the Health ABC study. Attached are the results from your bone density test from your Year 5 clinic visit. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this report is to help you and your doctor understand your bone density measurement.

What is a bone density measurement?

A bone density test measures how much calcium is contained in certain bones, such as the hip. In general, lower bone density and lower calcium means that the bone is weaker.

What do bone density measurements mean?

We all lose bone as we get older, but some people lose bone faster than others. Certain factors can reduce bone density, such as smoking, low calcium intake, lack of exercise, high alcohol intake, use of some medications, and some medical conditions.

Individuals with low bone density have weaker bones, and weaker bones are more likely to fracture during an accident (even a minor accident such as a fall). However, not all women and men with low bone density will have fractures and, occasionally, even those with high bone density will suffer a fracture.

What are my bone density results?

Your hip bone density value was compared to that of young men and is at the level checked below:

- _____ Normal
_____ Low
_____ Osteoporosis

If your bone density is checked as "low" or "osteoporosis," we suggest that you discuss these results with your personal doctor, and we would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a local doctor who specializes in treating osteoporosis.

If you have questions regarding these results, please contact _____ at _____.

[Men]

Muscle strength and walking speed tests

We do not know yet what results are considered “normal” for these tests. You are helping us understand how body changes may cause new health problems and how to prevent disability as we get older. In future years, with your continued participation, we may be able to tell you how your test results compare with others.

Knee crepitus

Knee crepitus is when a clicking, popping, or grinding is felt when you put your hand over your knee while you move your leg forward and backward. Knee crepitus is common in people with osteoarthritis of the knee, but it also occurs in people who do not have knee osteoarthritis. If a person has both knee pain and crepitus, they may have knee osteoarthritis. It is not known what it means to have crepitus without knee pain.

Treatments for osteoarthritis include medications to reduce pain and inflammation (aspirin and nonsteroidal antiinflammatory drugs), exercise, and for knee osteoarthritis, in particular, weight control.

Ultrasound

We do not know yet what results are considered “normal” for the ultrasound test. Low ultrasound measurements may be an indication of poor bone quality, but the exact meaning is unclear.

Memory and reaction time tests

There are no “normal” values for many of these tests. By repeating these tests in future visits you will help us learn more about how memory and reaction time changes with age and in relation to lifestyle and changes in health.

We would like to thank you for your continued participation in the Health ABC study. These tests were done for research purposes only and were not intended to diagnose any health problems. However, we encourage you to share these results with your doctor. If you have any questions, please call the Health ABC clinic at:

() _____.



HABC Enrollment ID #					Date of reading:				
H						/		/	
					Month	Day	Year		

KNEE RADIOGRAPH PARTICIPANT REPORT

Participant name: _____

This report describes what the HEALTH ABC arthritis specialist (rheumatologist) found when they looked at your knee x-rays. If you have any questions about this report, please contact your doctor. This exam was conducted for research purposes only, and was not performed to diagnose any medical conditions.

The examiners were looking for the following:

- Osteoarthritis** develops when the cartilage in the joints starts to wear away. This is usually accompanied by changes in the bone near the joint which can be seen on an x-ray. It is the most common form of arthritis.
- Osteophytes** are bony growths which form around a joint affected by osteoarthritis.
- Joint space** narrowing is a decrease in the space between the joints which occurs when the cartilage wears away.
- Cysts** are fluid-filled sacs in the bone near joints affected by osteoarthritis.

1 OSTEOARTHRITIS

A. Tibiofemoral joint

LEFT KNEE

RIGHT KNEE

Normal	<input type="checkbox"/>	<input type="checkbox"/>
Mild (definite osteophytes)	<input type="checkbox"/>	<input type="checkbox"/>
Moderate (osteophytes, definite loss of joint space, possible sclerosis and cysts)	<input type="checkbox"/>	<input type="checkbox"/>
Severe (large osteophytes, moderate to severe loss of joint space, definite sclerosis, cysts, or subluxation)	<input type="checkbox"/>	<input type="checkbox"/>

B. Patellofemoral joint

Normal	<input type="checkbox"/>	<input type="checkbox"/>
Mild (definite osteophytes)	<input type="checkbox"/>	<input type="checkbox"/>
Moderate (osteophytes, definite loss of joint space)	<input type="checkbox"/>	<input type="checkbox"/>
Severe (large osteophytes, moderate to severe loss of joint space, subluxation)	<input type="checkbox"/>	<input type="checkbox"/>

2 OTHER FINDINGS

Chondrocalcinosis	<input type="checkbox"/>	<input type="checkbox"/>
Paget's disease	<input type="checkbox"/>	<input type="checkbox"/>
Loose bodies (osteochondromatosis)	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>

Version 1.1, 9/24/98

APPENDIX 5

Excessive Bone Loss Form

	HABC Enrollment ID #	Acrostic	Date Form Completed	Staff ID #
	H		/ /	
			Month Day Year	

EXCESSIVE BONE LOSS FORM

Suspected Excessive Bone Loss Checklist

(Examiner Note: Please make sure that this form is accompanied by all the items listed below.)

- Printouts of the baseline and all follow-up scans of the hip
- Printouts of the "rate of change" report(s) you created for the hip
- Copies of baseline and all follow-up scans of the hip on floppy disk

Be sure to follow all procedures for participants with suspected excessive bone loss.

Comments: _____

To be filled out by the UCSF DXA Reading Center

- Yes, we can confirm excessive bone loss.
The scans are technically correct and the analyses are performed appropriately.
- Yes, we can confirm excessive bone loss.
However, the scans were not analyzed properly. Please reanalyze the scan(s) following our instructions and inform the participant of the correct bone loss %.
- The scans provided indicate possible excessive bone loss.
However, a second scan of the site was not performed in this participant. Excessive bone loss can only be confirmed after you have obtained a second scan of the region where bone loss is suspected. Please schedule the participant for a repeat measurement.
- After scan review we cannot confirm excessive bone loss.

Comments: _____

Signature of UCSF DXA Reading Center Reviewer _____ Date: _____



Version 1.0, 4/1/99

APPENDIX 6**Excessive Bone Loss Letter to Participant**

March 13, 2002

Jane Doe
1234 Market Street
Pittsburgh, PA 15213

Dear Ms. Doe:

During your last clinic visit for the Health ABC study, we repeated measurements of your hip bone density. Analysis of the results indicated that you have lost bone in the hip at a rate greater than 3 % per year since your baseline measurement was made.

This loss is greater than average for a person your age and may indicate an increased risk of fracture. This bone loss may also be related to other health conditions, or could result from use of certain medications.

We have enclosed both copies of your hip scan, your baseline measurement and your last measurement. We suggest that you consult with your personal doctor to find out why this is occurring, and we would be happy to forward these results to your doctor.

If you do not have a source of medical care, we can provide you with the name of a doctor who specializes in treating osteoporosis in Pittsburgh.

Thank you for your time and interest in the Health ABC study. Please do not hesitate to call us if you have questions at (_____) _____ and ask for _____.

Sincerely,

Anne Newman, M.D., M.P.H.
Health ABC Principal Investigator

/sa

APPENDIX 7

Excessive Bone Loss Letter to Physician

March 13, 2002

Abe Friedman, M.D.
5845 Centre Avenue
Pittsburgh, PA 15213

Dear Dr. Friedman:

Your patient, _____, who has been a participant in the Health ABC study for the past 5 years, was here on ___/___/___ for his/her annual visit. We have measured bone mineral density of the hip with state-of-the-art densitometry machines at baseline, Year 3, and now at Year 5. The BMD scans of his/her total hip showed _____% bone loss since the start of the study. Our study experts have reviewed these scans and believe the bone loss to be real. This is considered to be a significant amount and is referred to as “excessive bone loss” by our study. Significant declines in hip BMD may indicate the presence of an important medical condition, such as vitamin D deficiency or multiple myeloma, but we cannot rule out the possibility of positioning or other measurement errors.

We are enclosing a copy of the participant’s hip scan and reference plots that show the bone loss to be _____%.

If you have any questions, please feel free to contact us at (____)_____.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

/sa

APPENDIX 8**Weight Change Alert Letter for Physician**

September 13, 2001

Charles Cutler, M.D.
512 Hamilton Road
Marion, PA 19066

Dear Dr. Cutler:

On September 1, 2001, _____ was seen at the Health ABC Research Clinic.

At the last clinic visit one year ago, his/her weight was _____ lbs (kgs)
The weight today was _____ lbs (kgs)

This weight is $\geq 10\%$ less than one year ago.

All tests done for Health ABC were performed for research purposes only and will be used to describe the health status of men and women in their seventies and eighties who are taking part in this study. These tests are not intended to replace any tests that might be ordered for a specific clinical indication. Although we do not suggest a specific diagnosis or treatment, we hope this information is useful to you and your patient.

If you have any questions, please feel free to contact us at _____.
Thanks you for your support.

Sincerely,

Anne Newman, M.D., MPH
Health ABC Principal Investigator

Piera Kost

