DOCUMENTATION

for

ANKLE BRACHIAL INDEX (ABI)

in

MIDUS REFRESHER BIOMARKER PROJECT (P4)

University of Wisconsin ♦ Institute on Aging
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INTRODUCTION

This document provides an overview of the Ankle Brachial Index (ABI) data collected in the MIDUS-Refresher (MR) Biomarker Project (P4) data. This document describes the ABI protocol and measures. Administrative and computed variables are also identified and information about the construction and usage of these variables is included.

Data users are also encouraged to review the Refresher Biomarker (P4) Readme Data File Notes. This document provides information about naming conventions, as well as administrative and filter variables included in the data file. It also includes information about how we handled missing values and other issues that arose over the course of the study. For example, there are instances when variables were added or sections of an instrument were expanded for data entry purposes to accommodate additional information provided by the respondent.

This document will be periodically revised and updated as more information is gathered, and researchers continue to work with the MIDUS Biomarker data. If there are suggestions or comments, please contact midus_help@aging.wisc.edu.

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OVERVIEW OF DATA FILE AND COLLECTION PROTOCOL

The MIDUS Biomarker Project (P4) assesses Ankle Brachial Index using the Summit Doppler Vantage ABI™ system via blood pressure cuffs placed in four locations while the participant is lying down. At the end of a 5 minute resting period, the four cuffs are activated in rotation (right arm, right ankle, left arm, left ankle) with the device automatically inflating the cuff, measuring systolic pressure and deflating the cuff.

The ABI assessment was added to the MIDUS Biomarker Refresher protocol as a pilot project conducted only at Site 1 (UCLA). It was added because ABI can be an indication of peripheral vascular disease and is most prevalent in people who are older; those with diabetes are at particular risk. ABI is the ratio of systolic blood pressure in the arteries (typically measured at the ankle) to the brachial (upper arm) systolic blood pressure. [Ankle Brachial Index Collaboration, 2008]. These ratios assess the quality of the blood supply to each leg. Lower than normal values of ABI in one or more legs reflects stenoses in peripheral arteries, and is typically indicative of atherosclerotic disease. Generally, an ABI of 0.8 or less is considered low.

Since atherosclerosis is generally not confined to one vascular bed, low ABI is predictive of cardiovascular risk in general [Newman et al., 1993; Doobay & Anand, 2005]. Low ABI is correlated with atherosclerotic disease in other vascular beds, such as the carotid and coronary arteries [Zheng et al; McDermott et al. 2006], and even predicts risk for incident coronary events [Weatherly et al. 2007] and incident stroke [Abbott et al., 2001; Murabito et al., 2003]..
The following describes the summary measures reported and the data collection protocol.

As described in the "MIDUS Refresher Biomarker Project (P4) Readme Data File Notes", naming convention organizes variables according to data type or the method used for data collection. Following this convention, the first four characters of the ABI data are "RA4C".

Data Documentation

The following data are obtained during this protocol and reported separately for the right and left side

- Blood Pressure (BP) – Systolic BP as measured by the Vantage system at the ankle and upper arm (brachial) on the right and left sides.
- Ankle Brachial Index – ratio of ankle/brachial BP.
- The Vantage ABI™ automatically calculates the ABI for both sides. The right and left ABI are both calculated using the higher of the two brachial pressures (Summit Doppler Vantage ABI User Manual MAN0030A, p. 16). Thus,
    - ABI for a given side is *not* calculated if the ankle BP is missing on that side.
    - ABI *is* calculated for a given side if the ankle BP is available for that side and at least one brachial BP is available.
  - If a BP is missing, or ABI is not computed when a value would be expected, it is due to technical (software or equipment) problems.

The data file also includes the following flag/filter variables which can be used to select the subset of cases for which ABI data is available.

- RA4CABI – indicates whether ABI data is available for a given participant or not.
    - Note – this assessment was added to the Biomarker protocol several months after the Refresher data collection at Site 1 (UCLA) only, thus some UCLA participants, along with participants from the other two sites, will be coded as INAPP for this variable and all data values will be INAPP.
- RA4CA1 – indicates whether the assessment was completed on Day 1 or Day 2 of the visit.
- RA4C4 - indicates whether the table on which the participants laid down for the assessment was long enough that the participant's feet did not extend past the end of the table.
    - If this occurs then the BP may not be computed correctly.
- RA4C5 – Indicates whether the participant is missing a limb or not.
    - If a limb is missing the assessment is not done on that side.

The ABI data appear in the data file immediately after the Gait data.

References

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Zheng Z-J, Sharrett AR, Chambless LE, et al. Associations of ankle-brachial index with clinical coronary heart disease, stroke and preclinical carotid and popliteal atherosclerosis: The Atherosclerosis Risk in Communities (ARIC) Study. *Atherosclerosis* 131 (1997) 115–125.

SECTION B

ANKLE BRACHIAL INDEX TRACKING FORM

SECTION C

ANKLE BRACHIAL INDEX PROTOCOL

Ankle-Brachial Index
MIDUS Refresher
Manual of Procedures

Overview

The goal of this procedure is to measure ankle-brachial index (ABI) in MIDUS Refresher participants, using the Vantage ABI device manufactured by Summit Doppler. ABI can be an indication of peripheral vascular disease and is most prevalent in people who are older; those with diabetes are at particular risk.

Visit Preparation

In preparation for the visit, ensure that the following supplies are available:

- Vantage ABI device, along with four designated cuffs
- A suitable bed and pillow , covered with appropriate linen
- Disinfecting wipes
- MIDUS Refresher Tracking Form
- USB drive designated for this measurement

Measuring ABI

Outlined below are the standard steps for completing the ABI measurement. Details and troubleshooting suggestions can be found in the Vantage User Manual http://www.summitdoppler.com/site/files/969/110955/379258/533522/Summit_Doppler_Vantage_ABI_User_Manual_MAN0030A.pd

The order of measurements is determined by the software in the system. The right side will be done first, followed by the left side. ABI ratios are provided for each side of the body.

1. Administer the eligibility questionnaire. If there is an indication that the participant is not eligible for ABI measurement, do not proceed.

2. Ask the participant to remove socks and shoes. If the participant's shirt does not have loose fitting sleeves that allows placement of the cuff directly on skin, ask the participant to change into a gown (pants do not need to be removed).

3. Have the participant lay down on the exam bed. It is important for participants' feet to be in the same horizontal plane as their hearts. Most participants will find it comfortable to use a pillow for head support their. If the participant is too tall (long) for the table, please note that on the data collection form.

4. Place the cuffs snuggly on the arms and ankles. For proper placement, the tubing connection should be at the top or upper edge of the cuff. Follow the guide on the cuff for the correct location of the tubing on the artery.

5. Once the participant is correctly placed for the measurement, tell the participant to rest quietly for **5 minutes**. Explain that there should be little talking during this period and the measurement. If possible, leave the room to allow the participant to rest quietly.

6. Once the rest period is completed, come back to the room and inform the participant the measurement process will begin.

7. Turn on the Vantage (press the ON/OFF gray circular button). Hoses should already be connected. If not, connect as described in the manual and indicated on the back of the unit.

8. Input the participant ID:
   - Touch 'MENU'
   - Touch 'MENU OPTIONS'
   - Touch 'NEW EXAM'
   - Enter the participant ID on the keypad
   - Touch 'DONE'; the device will return to the main display screen

9. Confirm that the PVR waveform is turned off. If it is turned off, a large 'X' will appear next to 'PVR' between the arm and ankle measures on the display screen. If the display is not the 'X;, do the following:
   - Touch 'MENU' at the bottom right
   - Touch 'SYSTEM SETTINGS' at the top
   - Touch 'WAVEFORMS' at the bottom until the value is 'OFF'

10. Confirm that the Auto Inflation is set to '2'. This permits the arm and ankle cuff on one side of the body to be inflated at the same time. Check the settings by doing the following:
    - Touch 'MENU' at the bottom right
    - Touch 'SYSTEM SETTINGS' at the top
    - Touch 'AUTO INFLATION' until the value is '2'

11. Tell the participant you will be starting the measurement. On the main display screen, touch 'START'. The Vantage will begin inflation on the right side. Remind the participant to remain still.

12. The Vantage will automatically deflate the cuffs on the right side and conduct the full measurement on the left side.

13. Once the cuffs on the left side deflate, review the display to determine if there were any problems with obtaining ABI measurement:
    - A checkmark indicates successful measurement at the anatomic site
    - L <up arrow> indicates the pressure limit should be increased; refer to page 15 of the manual to modify the settings and remeasure the specific site
    - L <down arrow> indicates the pressure limit should be decreased; refer to page 15 of the manual to modify the settings and remeasure the specific site
    - NA indicates the signal was not usable, probably due to participant movement. Ensure the cuffs are placed appropriately and retake the measurements
    - AR indicates abnormal result were detected. Ensure the cuffs are placed appropriately and retake the measurements

14. Once all measurements are taken, remove all cuffs from the participant's limbs.

15. After completing all tasks with the participant for the day, transfer the data file to the USB drive:

- *BE SURE THE USB MEMORY STICK IS PLUGGED INTO THE SYSTEM PRIOR TO DOWNLOADING*
- Go to ‘EXAM MANAGEMENT’
- Touch the exam completed
- Touch ‘EXPORT’

Note: An “E” will appear next to that exam indicating that it has been previously exported to the USB. In “Exam Management”, touch the up arrow to scroll up through the list of saved exams. Touch the down arrow to scroll down through the list. Touch **ALL** to select all of the exams in the list. Touch **BACK** to return to the ABI main screen.

16. When back in the office, transfer the file from the USB drive to the folder N:\ABI\Data Files.