PhenX Toolkit

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

1. Did a doctor ever say that you had claudication or peripheral arterial disease (poor blood flow to the legs or blocked or narrowed arteries to the legs)? Do not include varicose veins or phlebitis.

0 [ ] No

1 [ ] Yes

If yes:

For the above condition have you ever had . . .

2. Angiography (dye in the arteries of the legs)?

0 [ ] No

1 [ ] Yes

3. Angioplasty (balloon catheter to open blockage)?

0 [ ] No

1 [ ] Yes

4. Surgery to improve blood flow in your legs (do not include surgery for varicose veins)?

0 [ ] No

1 [ ] Yes

5. Take blood pressure measurements to calculate the Ankle Brachial Index.

The presence of peripheral arterial disease (PAD) will be assessed with the ankle brachial index (ABI) for persons aged 45-74. A low ABI is a reproducible and valid measure of lower extremity arterial disease and has been shown to predict all-cause and cardiovascular mortality. A normal ABI is 1.00 to 1.40, with progressively

lower values below 1.00 corresponding to more severe arterial disease. Many persons in the group with an ABI >1.40 will also have PAD. These higher ABIs are uncommon and reflect medial arterial calcification and partial or complete incompressibility of blood vessels, and primarily occur in persons with diabetes.

Equipment and Supplies

- Two Nicolet Dopplers, Elite 100R, EN 50R with rechargeable batteries
- Two full tubes of ultrasound transmission gel
- Two aneroid sphygmomanometers, DS66 trigger type, #5098-30
- Eight Welch Allyn adult arm blood pressure (BP) cuffs, 2 piece, 1 tube bladder, #5082-43 (4 of these 8 will be for the ankle)
- Four large adult arm BP cuffs, 2 piece, 1 tube bladder, #5082-44
- Four thigh size BP cuffs, 2 piece, 1 tube bladder, #5082-77
- Tissue or wash cloth to remove ultrasound contact gel
- Non-toxic dry erase marker
- Ankle Brachial Index (ABI) form
- T-Spray (Pharmaceutical Innovations, Inc.) and/or Clorox® Disinfecting Wipes (both contain the same disinfectants)
- Tegaderm® (3M)
- Polylined towels (sterile drapes - multiple internet sources)

Note: Clorox® Disinfecting Wipes is a registered trademark of the Clorox Company

Tegaderm® is a Trademark of 3M Company (3M)

Definitions

1- PAD, peripheral vascular disease, peripheral atherosclerosis, lower extremity arterial disease, and peripheral arterial obstructive disease are synonyms. PAD does not refer to venous disease, small-artery obstructive disease, vasospastic disease, cold sensitivity, or capillary disease. For this protocol, PAD does not refer to carotid artery disease, or to other peripheral non-coronary atherosclerotic disease.

2- The ABI is a ratio of the ankle to arm systolic blood pressure (SBP), and is computed separately for each leg. Specifics of the ABI computation for HCHS/SOL are given below.

3- An ABI of 0.90 or less is generally considered PAD, although PAD could also be present if the ABI is 0.91 to 0.99, or >1.40.

Methods

<u>Preparation</u>

The ABI should always precede the blood draw. If for some reason it does not, see precautions below. Explain the procedure to the participant and allow him/her to ask questions. Conduct the examination in a quiet, warm, and comfortable room. If the room is cool, a blanket may be used to cover the participant (including arms, hands, and feet), except while the actual measurements are being made. Have the participant lie supine on a comfortable horizontal examination table. The head and heels must be at the same level, and therefore the table must be long enough so that for each participant, the entire head and both feet must be on the table, not overhanging. Because having the feet even slightly lower than the rest of the body will produce an invalid ABI measurement an oversized examination table must be available for tall study participants. Arms below the shoulder and legs below the knee should be bare.

Inspect all four blood pressure (BP) cuffs before placement and use only cuffs that are clean and dry. Do not place blood pressure cuffs over any lesion that could be a potential source of contamination. Do a visual exam and use a protective, non-penetrable covering over any such lesions. See below for specific instructions.

Have the participant rest quietly for at least 5 minutes before beginning the measurement procedure. The participant may be sitting or supine while resting.

While the participant is resting, place an appropriate BP cuff around both arms, based on arm circumference at midpoint. The general rule is that the cuff width must be at least 40% of the arm circumference. The 3 cuff sizes should be employed as follows:

- Adult for arm circumference of <32 cm
- Large adult for arm circumference of 32-42 cm
- Thigh for arm circumference of ≥43 cm

The widths of the bladder for "Adult", "Large Adult" and "Thigh" cuffs are 12, 16 and 20 cm, respectively. Please note that on the Welch Allen cuffs, there are numbers next to the names of the cuffs (e.g. "Adult 11" and "Large Adult 12"). These numbers do **not** correspond to the width of the cuff and should **not** be used to determine which cuff is placed on the arm.

Place an adult cuff size on each ankle. Place the cuff so that the tube is facing the torso, not the toes, and the lower portion rests 3 cm proximal to the greatest protuberance of the medial malleolus (ankle bone).

Once all four cuffs are in place and the 5 minutes of resting are complete, you may begin the measurements as described below.

Record the date of the examination on the ABI Form (see supplemental information for ABI Form, https://phenx.org/Default.aspx?tabid=482). Before you begin the procedure, instruct the participant to remain relaxed and to refrain from

helping you (e.g. lifting the arm to facilitate placement of the cuff). Once you begin the procedure, explain the steps to the participant as you proceed.

Arterial Blood Pressure Measurement

This step is optional, but will likely be necessary in some participants: By palpation, locate the brachial artery on both arms (antecubital fossa), and the dorsalis pedis (dorsum of the foot and often in direct line with the 2nd toe) and posterior tibial (medial ankle just behind the medial malleolus) arteries on both legs. Mark the location of each artery with a marker. Sometimes an arm or ankle pulse will not be palpable but can be found with the Doppler.

SCRIPT: "With water-soluble ink, I am going to mark the location of your arteries for the blood pressure measurements."

Using the procedure below, measure systolic blood pressures (SBP) in the following order on the ABI form:

1. Right brachial artery (Q1a)

2. Right dorsalis pedis artery (Q1b)

3. Right posterior tibial artery (Q1c)

4. Left posterior tibial artery (Q1d)

5. Left dorsalis pedis artery (Q1e)

6. Left brachial artery (Q1f)

Place an appropriate amount of ultrasound conducting gel over the end of the Doppler.

On occasion, there may be skin lesions on the arms, legs or at the insonation site that are of concern for performing the measurement of the systolic blood pressure. In these instances, we recommend the following procedures be followed in an effort to reduce the potential for contact with blood borne pathogens.

1. For major open lesions, omit the BP measurement in the affected extremity. For minor lesions that are a potential source of contamination (lacerations, abrasions, rash, etc.) at the site for placement of the blood pressure cuff, either arm or leg, wrap the affected area with a polylined towel (i.e. sterile drape). Then wrap the blood pressure cuff around this towel and conduct the pressure measurement as described.
2. For lesions with contamination potential at an insonation site, do not perform the Doppler measurement at the affected site.
3. For the specific circumstance when the lesion is a venous puncture due to a

blood draw performed before the ABI measurement, apply a Tegaderm dressing over the puncture site and perform the measurement as described. In this situation, the Doppler probe should be cleaned with T-Spray or a Clorox Disinfecting Wipe both *before and after* insonation.

After palpating the location of the pulse, turn on the Doppler and place the probe over the artery. With this large probe, careful angulation is not necessary. Place the probe in line with the artery and move it from side to side until the strongest pulse is heard. Dont press too hard on the artery with the probe. Rest your hand comfortably so that the probe is secured in place once a strong pulse is heard. Then proceed to explain the procedure to the participant and ask if the participant has any questions before the measurements begin. If applicable, suggest to the participant to rest comfortably and to be quiet.

In a small percentage of participants, you may not be able to find the posterior tibial or dorsalis pedis pulse. If you are having trouble, be patient and continue to search for at least three minutes. If you are still unable to locate a pulse, enter a systolic pressure of "000" for that artery.

Inflate the cuff until the pulse is no longer audible. **Inflate to 20 mm Hg above the level at which the pulse sound disappears.** (If the pulse cannot be obliterated, you may raise pressure to a maximum of 300 mm Hg. If not obliterated at that point, record "300"). Deflate the cuff slowly allowing the pressure to drop at a rate of **2 mm Hg per second.**

Record the pressure at which the first sustained (more than one beat) pulse reappears. This is the SBP at this location. Deflate the cuff completely. *Record the measurement on the ABI Form immediately.* Then repeat the process to obtain a pressure measurement at each of the remaining sites.

If the signal remains faint as more pressure is released or if the probe moves off the artery, deflate the cuff completely, and then repeat the measurement.

After completing the ABI measurements, thoroughly clean the Doppler probe with T-Spray or a Clorox Disinfecting Wipe. Please note that the Doppler must be completely clean and dry between participants.

Important note: record "000" for arteries where the pressure is not detectable and record "300" also for arteries that are not compressible as the highest pressure attempted (typically "300"). For arteries that could not be assessed, record "===".

In item 2 of the ABI form/screen record "completed successfully" if all 6 pressures were obtained as specified above. If one or more ankle arteries could not be obtained, and thus the pressure is listed as "===", specify the responsible condition(s) in item 3 of the ABI form.

Calculation of the ABI

computer program will calculate the ABI from your measurements. For your information, the procedure is given below.

The ABI denominator - There is only one ABI denominator per participant for both the left and right ABIs. This denominator is the higher arm SBP.

The right ABI numerator is defined as the higher of 1) the right posterior tibial SBP or 2) the right dorsalis pedis SBP.

The left ABI numerator is defined as the higher of 1) the left posterior tibial SBP or 2) the left dorsalis pedis SBP.

The right ABI is the right ABI numerator divided by the ABI denominator.

The left ABI is the left ABI numerator divided by the ABI denominator.

Risk Factor Guidelines

ACC/AHA 2005 Practice Guidelines for the Management of Patients with Peripheral Arterial Disease (lower extremity, renal, mesenteric, and abdominal aortic):

Table 1. Individuals at Risk for Lower Extremity Peripheral Arterial Disease

- Age less than 50 years, with diabetes and one other atherosclerosis risk factor
- Age 50 to 69 years and history of smoking or diabetes
- Age 70 years and older
- Leg symptoms with exertion (suggestive of claudication) or ischemic rest pain
- Abnormal lower extremity pulse examination
- Known atherosclerotic coronary, carotid, or renal artery disease