PERIPHERAL NEUROPATHY: MONOFILAMENT TESTING

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1. Background and rationale

Decrements in peripheral nerve function are known to increase both with advancing age and in the presence of diabetes mellitus. Since peripheral neuropathy (PN) involves both sensory and motor functions, PN may be associated with decrements in balance, strength and mobility, all disability-related outcomes that are central to the scientific objectives of Health ABC. Supporting a potential association between PN and various aspects of physical function in old age are several small studies in older adults that have suggested these effects. PN may be related both to performance tests and strength measures in the lower extremity, and are of equal scientific importance in older individuals with and without diabetes. Measures of PN in Health ABC include standard tests that have been used in other epidemiologic studies, and involve measurement of both sensory and motor nerve function. PN measurements are divided into three parts:

- Quantitative sensory testing (QST) of the great toe using the Medoc vibration device,
- Nerve conduction (NC) studies using the NeuroMax 8 to measure several parameters associated with the peroneal nerve, and
- Testing of loss of protective sensation using the monofilament.

General description of monofilament testing

The monofilament is a small instrument containing a thin nylon thread that runs perpendicular to the pen-like handle. Monofilaments come in different diameters, and when applied to the foot to the point that the wire bends, apply a precise and highly calibrated pressure to the surface of the foot. More pressure is applied by thicker threads, and less by thinner threads. Monofilaments are used to evaluate 1) loss of protective sensation, a clinically relevant risk factor for ulcers and amputation and 2) presence or absence of normal light touch sensation, an indicator of the state of peripheral nerve function. A two-step monofilament protocol is used in Health ABC. This protocol provides information that is both clinically relevant to the Health ABC population, and is an extension of more complex studies of peripheral nerve function. Monofilament testing will be done on the dorsum of the right great toe immediately following completion of peroneal nerve conduction studies.

The monofilament is a widely accepted diagnostic tool to evaluate loss of protective sensation that often leads to ulcer, and this information can be reported to participants' care providers. The Health ABC monofilament protocol focuses on a single site on the dorsum of the right great toe, and employs two monofilaments: The 5.07 monofilament

(providing a standardized 10g force) and the 4.17 monofilament (providing a standard force of 1.4 g). The 5.07 monofilament is the standard used to test for loss of protective sensation. Inability to detect the 5.07 is considered very abnormal. The 4.17 monofilament is the standard used to determine whether the participant has normal light touch sensation. Inability to detect the 4.17 may indicate early neuropathy. The protocol begins with the 4.17, and if the participant cannot feel that monofilament, he or she is tested with the 5.07.

2. Equipment and supplies

5.07 and 4.17 monofilaments (North Coast Medical, Inc.)

3. Safety issues and exclusions

Participants are excluded if they are missing both great toes (e.g., both great toes have been amputated).

4. Participant preparation

Monofilament testing will be conducted immediately following peroneal nerve conduction testing for two reasons. First, the participant already has the right leg exposed and prepared for testing, and second, the participant cannot see the testing performed from the supine position. There is no temperature requirement for monofilament testing. Prior to testing, the examiner should explain the testing procedure to the participant, show him or her the monofilament, and demonstrate the bending of the instrument on the participant's arm.

Testing with the monofilament occurs at a single site on the dorsum of the right gret toe, 1 cm proximal to the nail bed. Do not apply the monofilament to the knuckle of the toe.

5. Detailed measurement procedures

Describe the test to the participant, and allow them to become familiar with the monofilament.

Script: "This test is to see if you can feel a light touch on your toe. We press this flexible nylon thread ***(show monofilament)*** against your toe to see if you can feel it. It does not hurt, but it might tickle a little when you feel it. ***(Demonstrate on participant's arm).*** I'm going to touch the thread to your toe several times, and you just need to tell me if and when you feel the thread. Please close your eyes. I'm going to start the test."

Test using 4.17 monofilament on the dorsum of the right great toe. Apply the monofilament four times and count the number of times the participant feels it.

Script: "Tell me each time you feel the thread."

If the participant detects the 4.17 monofilament at least three of four times, do not continue testing with the 5.07 monofilament. If the participant does not detect the 4.17 monofilament at least three times, test with the 5.07 monofilament in the same way (four trials).

Record which great toe was tested on the data collection form; if the test was not done, record why the participant was not tested.

Record whether or not the participant was able to detect light touch with the 4.17 monofilament at least three of four times, and if they were not able to detect light touch with the 4.17 monofilament, record whether or not they were able to detect light touch with the 5.07 monofilament at least three of four times.

6. Procedures for performing the measurements at home (if applicable)

The same procedures described above may be performed at home.

7. Alert values/Follow-up/Reporting to participants

The results of the monofilament test are included in the Year 4 Participant Results Form. If the participant can feel the 5.07 or the 4.17 monofilament, mark the checkbox that says : "The monofilament test was normal." If participant does not detect the 5.07, after not detecting the 4.17 monofilament, mark the checkbox that says: "The monofilament was not felt." The participants are encouraged to share their results with their doctor.

8. Quality assurance

8.1 Training requirements

The examiner required no special qualifications or experience to perform this assessment. Training should include:

- Read and study manual
- Attend Health ABC training session on measurement techniques
- Practice measurement protocol on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

8.2 Certification requirements

- Complete training requirements
- Conduct exam on two volunteers:
  - According to protocol, as demonstrated by completed QC checklist

8.3 Quality assurance checklist

☐ Main points of script correctly and clearly delivered
☐ Correctly describes testing procedure
☐ Demonstrates monofilament on participant's arm
☐ Correctly tests using 4.17 monofilament
☐ Correctly determines whether or not to test with the 5.07 monofilament (i.e., only if participant cannot detect 4.17 monofilament)
☐ Reviews form for completeness following completion of test