NHANES 2001-2002 Data Release May 2004 MEC Examination

Peripheral Neuropathy (PN) Section of the Lower Extremity Disease Examination (LEXPN_B)

Survey Years Included in this File:

2001-2002

Component Description:

The Lower Extremity Disease Examination data will be used to determine the prevalence of lower extremity disease in the U.S. population (diagnosed and undiagnosed), including those at high risk for the late complications of the disease (i.e., ulceration and amputation). The major manifestations of lower extremity disease are peripheral vascular disease and peripheral neuropathy. The Ankle Brachial Blood Pressure Index section of the Lower Extremity Disease component collects data on peripheral vascular disease and the Peripheral Neuropathy (PN) section of the Lower Extremity Disease component collects data on peripheral neuropathy. The following documentation provides information on the PN section. Please refer to the LEXAB_B data file, codebook, and documentation for information on the Ankle Brachial Blood Pressure Index section.

Eligible Sample and Component-Specific Exclusions:

Participants 40 years of age and older are asked to participate in the PN Section of the Lower Extremity Disease examination.

Persons are excluded from the exam if they have a bilateral amputation or weigh over 400 pounds (due to equipment limitations). Additionally, some persons who were eligible for the exam (40 years of age and older) might not have received the exam due to the following multiple reasons: 1) casts, ulcers, dressings, or other conditions of the participant interfered with testing, 2) participant could not understand the test instructions, 3) participant became ill and the test could not be performed, 4) there was an equipment failure, 5) participant refused, 6) participant came late or left early from the MEC and the LED exam could not be performed, or 7) some other reason. As a result, these eligible persons will have missing data for the ABPI variables. The variable LEDSCCT1 may be used to identify reasons for missing data (refer to Component-Specific Analytic Notes section of this documentation for further details on the LEDSCCT1 variable). Due to participant confidentiality and data disclosure concerns, this file does not identify persons with a bilateral amputation. However, information on right or left amputations of the feet and toes is recorded in variables LEALAMP and LEARAMP.

Examination Protocol:

The PN exam was performed by trained health technicians in a specially equipped room in the mobile examination center (MEC). Participants lie supine on the exam table during the exam. Health technicians use a standard monofilament (5.07 Semmes-Weinstein nylon monofilament mounted on a plastic handle; Delivers approximately a 10-gram filament force) to apply slight pressure to the bottom of each of the participant's feet at the following 3 sites: 1) plantar-first metatarsal head, 2) plantar-fifth metatarsal head, and 3) plantar-hallux. The sites are tested in a nonsequential order to allow for better discrimination of sensation by the examinee.

Health technicians read the following standard script (English version) to the participant prior to application of the monofilament:

"I want to test the sensation or sense of touch on the bottom of your feet. To do this test, I will use this small filament to apply pressure to different spots on your foot. It is not sharp and will not break the skin. "

"As I apply the pressure I will be saying 'A, B' and I will be applying the pressure <u>either</u> as I am saying 'A' <u>or</u> as I am saying 'B'. I want you to tell me whether you felt the pressure when I said 'A' or when I said 'B'. Let me demonstrate on your arm."

"Do you understand?"

This method presents the examinee with a choice between an interval of stimulus from the monofilament and a second interval of background with no stimulus. The choice is to identify in which interval the stimulus occurred, not whether or not it occurred. The computer randomly generates the interval in which the stimulus is applied.

If the first response at any site is correct, the test is not repeated at that site. If the examinee cannot correctly identify the interval in which the stimulus was applied (incorrect or 'unable to determine' response), the test is repeated at that site up to two times until a total of two similar responses are obtained (incorrect and 'unable to determine' are considered similar responses).

The feet are also examined for the presence of amputations, lesions, and bunions.

Refer to Lower Extremity Disease Procedures Manual (1) for further details.

Quality Control during Data Collection:

Health technicians were regularly monitored by MEC supervisory staff and evaluated by experienced trainers and NCHS staff two to four times per year in the field. Retraining sessions were conducted with the technicians periodically and annually to reinforce the proper protocols and technique. Data were also routinely examined by NCHS and contractor staff. Inspection, calibration, and maintenance of the equipment and supplies were performed on a regular basis. The NHANES Lower Extremity Disease Procedures Manual (1) details the equipment quality control procedures.

Data Processing and Editing:

The number of insensate areas on the left (LEALPN) and right (LEARPN) foot were automatically computed by the computer system and verified by NCHS before data release.

Calculation of number of insensate areas for variables LEALPN and LEARPN:

Nine variables go into the calculation of each variable (up to 3 tests at each of 3 sites). Each of the 3 sites is first defined as sensate or insensate.

Sensate: A site is defined as sensate if 1) the first response at a site by a participant is correct or 2) two out of three tests at a site yield a correct response.

Insensate: A site is considered insensate if there are 1) two incorrect responses, 2) two 'unable to determine' responses, or 1) 1 incorrect and 1 'unable to determine' response for a site.

After each of the 3 sites is defined as sensate or insensate, then the total number of insensate sites is computed for each foot (0-3 insensate areas). If all 3 sites on a foot are sensate then there are 'no insensate areas' and a value of 0 (zero) is recorded. If all 3 sites have a "could not obtain (CNO)" then there is insufficient information to calculate the number of insensate areas and the recorded value for number of insensate areas will equal –1, not enough information collected. Additionally, even if 1 site gets a CNO and the other 2 are correct or incorrect/unable to determine, the overall value for number of insensate areas will still be -1. Missing data at all 3 sites can also yield a -1.

Refer to the NHANES Lower Extremity Disease Procedures Manual (1) for further details on how the values for these variables were computed.

Variable specific editing:

LEDSCCT1 – PN Section Comment Variable

This variable is a quality control variable that NCHS used to monitor the LED component and the reasons technicians provided for why an exam was not done or incomplete. Technicians were provided a defined list of reasons but could also select "other, specify" and provide the reason for a not done or incomplete exam in a separate text field. Several of these "other" reasons were re-coded to one of the specific reasons (1-104) for data release and the remaining were left as "other".

Component-Specific Analytic Notes and File Variables:

For the monofilament testing, the participant can give a correct, incorrect, or 'unable to determine' response. 'Could not obtain' can be entered by a health technician if they were unable to test the site either because of technician error or some physical limitation of the examinee (e.g., lesions, calluses, bandages, etc. on the test site). A response of 'Could not obtain' at any of the 3 sites on a foot does not provide any information about the sensation at that site.

LEDSCCT1 – PN Section Comment Variable

This variable is a quality control variable that allowed NCHS to monitor the component and the reasons technicians provided for why an exam was not done or incomplete. The data were not collected for analytic reasons but for quality control purposes. This variable is provided in the data release file to allow analysts to have some information on missing data and possible reasons for non-response.

NCHS Research Data Center:

No data from this component are in the Research Data Center.

Reference:

1. National Center for Health Statistics. Lower Extremity Disease Procedures Manual. January 2002. <u>http://www.cdc.gov/nchs/data/nhanes/le.pdf</u>