Attachment 12a

Blood Pressure Methodology Phase 1

Form Approved OMB No. 0920-0950 Exp. Date xx/xx/20xx

Assurance of Confidentiality – All information which would permit identification of an individual, a practice, or an establishment will be held confidential, will be used only by NCHS staff, contractors, and agents only when required and with necessary controls, and will not be disclosed or released to other persons without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 USC 242m) and the Confidential Information Protection and Statistical Efficiency Act (PL-107-347). By law, every employee as well as every agent has taken an oath and is subject to a jail term of up to five years, a fine of up to $250,000, or both if he or she willfully discloses ANY identifiable information about you.

Blood Pressure Methodology Phase 1

Justification for the Study

The ways of obtaining BP have changed remarkably in the last 20 years. Clinical BP, the category in which the National Health and Nutrition Examination Survey (NHANES) blood pressure (BP) method falls in, is no longer the only approach to obtaining accurate BP, both 24-hour ambulatory BP monitoring and home BP monitoring are acknowledged ways to obtain BP. All of these methods are presently use oscillometric automatic BP devices. Moreover, with the exception of the Framingham Heart Study and NHANES, other epidemiological studies use oscillometric automated devices to obtain BP values (1-6). Before a change can be made we need to better understand how BP measurements compare between the two types of devices and develop analytic methods to compare measurements obtained from the two devices. Measurements taken by the mercury device must be compared to those taken by a successor device so that secular trends of hypertension prevalence can be accurately maintained and followed.

We are proposing to conduct this study in the NHANES 2017-2018 survey cycle. A two phases study will be enable us to transition smoothly from the mercury to the automatic device. The first phase to be executed in NHANES 2017 will compare devices by selected covariates and the second phase to be executed in NHANES 2018 will compare high BP prevalence based on mean systolic and diastolic BP values obtained independently by the mercury device and Omron device. Whereas the first phase of the study will use data obtained from a selected sample, the second phase will be based on data of all eligible participants during one year of NHANES study.

It is expected that the final decision to change devices will be a decision to be derived jointly by National Heart Lung and Blood Institute (NHLBI), NHANES and the National Center for Health Statistics (NCHS). More specifically, after each phase of the study the results will be presented to appropriate stakeholders from NHLBI and NHANES/NCHS according to their

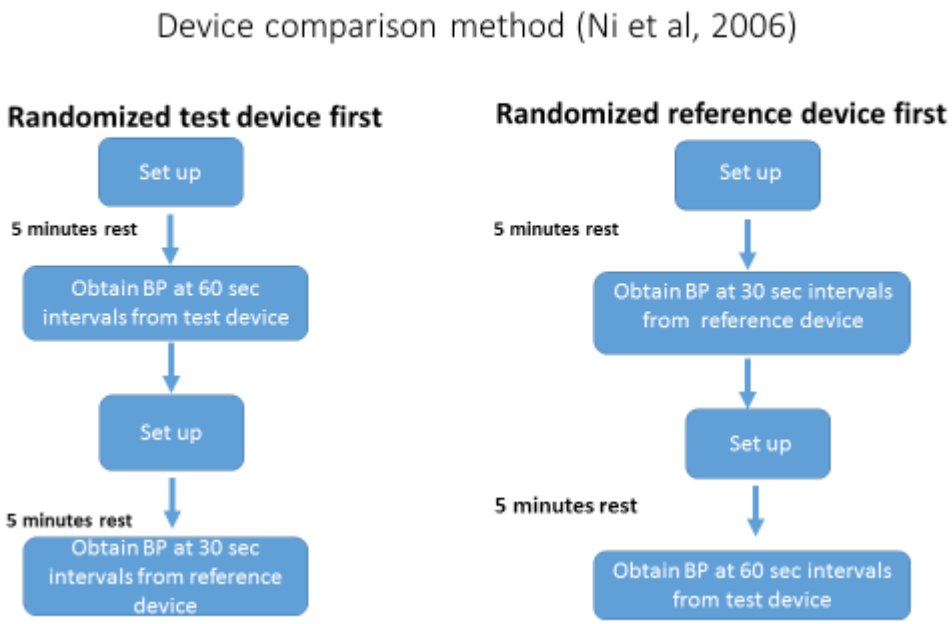
decision we will decide on go-or-no-go to the next phase. The decision rules are described in the statistic section of the proposal.

Eligibility: All NHANES participants ages 6 and older who participate in the mobile examination center (MEC) blood pressure measurements component are eligible. The maximum number of respondents would be 702.

Informed Consent: Written informed consent will be obtained as part of the regular NHANES consent process for the examination in the MEC.

Exclusion Criteria: There are no exclusion criteria except those already in place for the regular NHANES Blood Pressure MEC component.

Data Collection: This study will follow Ni et al (2006) device comparison method study (7). The overall schema for our method study requires 5 minutes of rest prior to obtaining BP measurements from the reference or the test device, order randomized, followed by another 5 minutes of rest prior to obtaining BP measurements from the test (hereafter Omron) or the reference device (hereafter mercury). The interval between BP determinations for the mercury will be 30 seconds; whereas, the interval for the Omron device is 60 seconds. Following this schema will enable us to accomplish 3 objectives. First, to maintain the legacy protocol for the mercury reference device. Second, to obtain BP measurements at 60-second intervals with the Omron device aligns the protocol with national and international standards which require 60-second intervals between sequential BP test devices measurements (8-10). Lastly, provide us enough time to change cuffs between the mercury and the Omron. Figure 1 describes the device comparison study design.
Figure 1



The study will require a two-stage randomization schema; specifically, the first randomization will assign the order of devices used in the randomized arms: mercury device first or the Omron device first. The second randomization will be to determine who, among the two technicians, will be the active observer, see Figure 2.

The active observer will perform the pre-measurement procedures. The pre-measurement procedures consist of all procedures prior to BP observations, specifically, positioning the participants, placing and changing the appropriate BP cuff on the upper arm, obtaining the maximum inflation level (MIL) in mercury condition, and initiating the 5-minute wait.

During the measurement procedure in the mercury condition, the active observer will be responsible for placing the stethoscope bell over the brachial artery, controlling the deflation valve and auscultating the BP using a double-headed stethoscope, observing the mercury column, and recording the 3 reference readings (systolic K1 and diastolic K5) at 30-second intervals. The active observer will be masked from the passive observer readings and Omron device readings. During the measurement procedure in Omron device condition, the active observer will make sure that the Omron device is in "hide" mode, initiate the Omron devices readings in automatic mode, and ensure that the 3 consecutive BP readings are done in 60-second intervals.

The passive observer has two tasks, first simultaneously with the active observer he/she will auscultate the BP using a double-headed stethoscope, observing the mercury column, and will record the 3 mercury readings (systolic K1 and diastolic K5) at 30-second intervals while being masked from the active observer readings and test device readings.

The total component time is expected to be 20-30 minutes. Once the 6 BP measurements are captured, the results will be recorded (double-keyed) by the revealer, who is trained to record the pressures from the machine so as to mask the results from the two observers.

Report of Findings: Findings from the blood pressure methodology study will not be reported to participants. Participants will receive blood pressure results from their regular NHANES blood pressure measurements.

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