

National Health and Nutrition Examination Survey

OMB No. 0920-0950

(Expires November 30, 2016)

Nonsubstantive Change Request to conduct the National Health and Nutrition Examination Survey (NHANES) Comparisons of Waist Circumference Measurements Pilot Study

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Friday, April 17, 2015

The National Health and Nutrition Examination Survey (NHANES) Comparisons of Waist Circumference (WC) Measurement Pilot Study

This is a request for a nonsubstantive change to the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0950, exp. November 30, 2016), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), to conduct a pilot/ methodological study. The proposed changes would not alter the currently approved burden hours.

A high WC is associated with an increased risk for type-2 diabetes, high cholesterol, high blood pressure, and heart disease. High WC reflects abdominal obesity, one of the grouped risk factors included in most definitions of metabolic syndrome (1-9). Different protocols may result in different abdominal obesity prevalence.

Currently, NHANES obtains WC using the standard NHANES WC protocol. The proposed pilot study will collect four additional WC measurements using two other protocols: the World Health Organization (WHO) protocol and the Multi-Ethnic Study of Atherosclerosis (MESA) protocol. The pilot study population will be NHANES participants aged 20 and over who participate in the body measurements component in the Mobile Examination Center (MEC). The WHO protocol will be performed once by a trained health technician. The MESA protocol will be performed twice by a trained health technician (once using the Gulick II Plus tape, and once using the Lufkin tape), and again by the sample participant using the Gulick II Plus tape as a coached self-measurement.

Each protocol measures WC at a different anatomical landmark. NHANES- WC measures WC at the level of the iliac crest as recommended by the National Heart, Lung, and Blood Institute (NHLBI). The World Health Organization (WHO) measures WC at the mid-point between the highest point of the iliac crest and the lowest rib. The WHO-WC method is often used in European health surveys and was used in the Korean National Health and Nutrition Examination Survey (10-12). The NHLBI sponsored Multi-Ethnic Study of Atherosclerosis (MESA) measures WC at the level of the umbilicus and can also be self-measured by study participants on cloth (13).

Out of the three WC at a different anatomical landmark, the MESA-WC is the least intrusive; therefore, enabling us to consider doing the measure as part of a home exam. Obtaining sub-national abdominal obesity data estimates will require a home exam-based WC measurement. Considering how important this risk factor is, it will be beneficial to operationalize MESA-WC first on a small scale. Our intention will be to do MESA-WC on clothing where the individual applies the tape but is coached by a health technician (HT) on how to do it correctly. We envision that a household interviewer (e.g. NHIS interviewer) will be able to coach an individual on how to take the measure in the most accurate way with little intrusion into individual privacy. More specifically, we will use the MEC environment to simulate the home exam environment and modify MESA-WC from completely self-measurement to coached self-measurement for the sake of more accurate standardized measurement of WC. The protocol also requires that the HT measure the thickness of the participants' clothes with a caliper. This pilot and the main study, if

done, would be the first step in validating the accuracy of self-measurement of WC and determining if it is necessary to measure the thickness of clothes. Finally, the order in which each waist circumference measurement is taken will be randomized.

Two tapes are commonly used for measuring waist circumference: the Gulick II Plus tape and the Lufkin tapes. The MESA-WC uses the Gulick II Plus tape. This tape measure provides 4oz. of tension to the tape and does not retract automatically. The NHANES-WC and WHO-WC uses Lufkin tapes. The Lufkin tape is an ordinary tape measure, in which tension will depend on how tightly the tape is pulled and it does automatically retract. These tapes will be compared for the MESA protocol only when measurements are taken by the health technician. The order of the tapes used will be randomized.

The intended sample will include individuals 20 years and older who are already participants in the NHANES Mobile Exam Center (MEC) body measurement component. The goal will be to have an approximately equal number of male and female participants. The maximum number of participants is 530.

A. Justification

1. Circumstances Making the Collection of Information Necessary.

NHANES contributes to the mission of CDC by collecting objective data that are used to promote health and to prevent and control disease and disability. CDC works with partners throughout the nation and the world to monitor public health, formulate and implement prevention strategies, develop health policies, promote healthy behaviors, and foster safe and healthful environments. In addition to the groups within the CDC, NCHS collaborates with over two dozen federal agencies to plan and fund the NHANES. The survey partners include numerous institutes of the National Institutes of Health, several programs within the U.S. Department of Agriculture, the Food and Drug Administration, and the U.S. Environmental Protection Agency. NHANES data are used to assess environmental exposures, evaluate nutrition program and policy impacts, and estimate the prevalence of health risk factors, chronic conditions, and infectious diseases.

NHANES is a continuous survey, meaning survey data are collected every year. It includes a household interview, done in participants' homes and physical measures and additional interviews done at the NHANES MEC. There may also be follow-up interviews or components (such as a 2nd dietary interview or the physical activity monitor (PAM)) that take place after the MEC exam. A major advantage of continuous NHANES data collection is the ability to address emerging public health issues and provide objective data on more health conditions and issues. Because of the NHANES sample design, data are released in two year cycles. Some of the survey information gathered may change at the beginning of each two year cycle. In some cases, this means new content will be added. In other cases, this means that existing content may be modified.

New methodology must be tested before being implemented. There are many reasons for this.

This allows us to find out how long the procedure being tested will take or how well received the procedure will be among our participants. The results of such testing also allow the NHANES program to make changes or adjustments to improve the methodology. It also provides hands on training opportunities for NHANES survey staff responsible for collecting the data. Testing is a vital step in making sure NHANES is effective and efficient in its use of resources. Despite a number of existing studies that compare various WC measurement procedures, there is apparently no previous study that compared coached self-measured WC using the MESA–WC protocol and either the NHANES–WC or the WHO–WC measurement procedures. Besides, a population-based methodology study comparing the three methods would be desirable. This study will try to close this knowledge gap. Such measures promote improved data quality once the data are collected in an actual survey. Since data collection is continuous, methodology studies must be conducted during ongoing NHANES data collection.

Objectives

Pilot

To determine the operational feasibility of collecting WC measurements according to three WC protocols within the existing NHANES.

Main Study

1. Compare WC measurement values obtained by three methods (NHANES–WC, WHO–WC, and MESA–WC) according to body mass index categories (BMI)¹ by gender and possibly other demographic characteristics, such as race/ethnicity.
 2. Compare the Gulick II Plus tape and the Lufkin tape from the MESA-WC Health Technician measurements.
 3. Compare abdominal obesity classification agreement² among the three different WC protocols.
 4. Provide cross-over prediction equations among the three WC protocols.
 5. Evaluate MESA-WC a coached self-measurement for potential use in a home exam setting.
2. Purpose and Use of the Information Collection

This proposal is to conduct a WC methodology pilot study in one stand in survey year 2015. We estimate that up 530 individuals will participate in the pilot methodology study. There is no intention to replace the current NHANES–WC in the regular NHANES or to add other measures at this time. Our intent for this study is to compare and develop the cross over equations. This OMB request is only for the pilot. If the pilot is successful, any proposed changes to the NHANES main study will be submitted to OMB for review and approval before such changes are implemented. It should be noted that as waist circumference is an existing NHANES component, no changes to the consent form or the health measurements list are required.

¹ Healthy weight is BMI (kg/meters²) of 18.5- < 25, overweight is BMI of 25-29.9, and obese is BMI \geq 30.

² WC \geq 102 cm (for men) or \geq 88 cm (for women).

Some recent studies provide crossover calibration equations between certain WC measurement methods. Statistics Canada used both the WHO–WC and the NHANES–WC methods during a recent 2-year survey cycle for a subsample of adult men and women aged 20–79 (14). Mason and Katzmarzyk (2009) provided crossover calibration equations for both the NHANES–WC measures using the WHO–WC measures and the WHO–WC measures using the NHANES–WC measures, but their sample was small and consisted primarily of non-Hispanic white persons (15). Another recent study using both the NHANES–WC and the WHO–WC protocols provided calibration equations only for WHO–WC to NHANES–WC and the study participants were not racially and ethnically diverse (16). For more information, read Ross et al (2008). This article provides a comprehensive review on the association between different WC measurement and mortality and morbidity (17). Parenthetically, their findings suggested that no WC protocol was superior in predicting cardiovascular disease, diabetes, or mortality (17).

Notwithstanding the above, to date, cross over equations are not systematically available for all three WC methods. And, despite a number of existing studies that compare various WC measurement procedures, there is apparently no previous study that compared technician coached self-measured WC using the MESA–WC protocol and either the NHANES–WC or the WHO–WC measurement procedures. This study will try to close this knowledge gap. Therefore, a population-based methodology study comparing the three methods would be desirable to: 1) facilitate comparisons between values obtained from NHANES–WC and from WHO–WC; 2) examine the comparability of a coached self-measured MESA–WC over clothing at the umbilicus to NHANES–WC and WHO–WC measurements; and 3) examine the comparability of a coached self-measured MESA–WC over clothing at the umbilicus to MESA–WC at the umbilicus over the skin done by a trained technician. All measurements will be done in the MEC.

If successful, a full study based on these protocols will be considered in the NHANES 2016 data collection year. There is no intention to replace the current NHANES–WC in the regular NHANES or to add other measures at this time.

B. Design of the Pilot

The current NHANES protocol would be modified as follows:

1. Before changing into MEC exam gown or before leaving the MEC after changing back into street clothes, the health technician (HT) will give eligible participants a brief explanation and a demonstration of doing a self-measured MESA–WC using a Gulick II Plus tape. HTs will also measure the thickness of clothing on all participants. That measurement will be obtained by using a caliper and recording the measurement to the nearest millimeter. This measure will be able to provide us with the ability to account for as much as possible for cloth thickness and to determine if measurement of clothing thickness is needed to obtain an accurate measurement. Then, the participant will be asked to put the tape measure around the waist at the level of the umbilicus to obtain a coached self-measured MESA–WC. The self-measurement will be observed that it is done correctly by the HT, and then the HT will record the results off the tape measurement to the nearest 0.1 cm. If the participant could not obtain the measurement correctly for not understanding the verbal instructions, the HT will code “Not done” for the self-measured MESA–WC.

2. The WHO–WC and MESA–WC measurements will be added to the current anthropometry component (body measures) in the MEC. It will be performed at the same time the current NHANES–WC measurement is taken. The NHANES–WC, WHO–WC, and MESA–WC will be randomized and measurements will be taken directly on the skin. The MESA–WC obtained on the skin will be taken twice in a random order, once using a Lufkin tape and once using Gulick II Plus tape measure. The waist circumference component of the NHANES ISIS system will be updated with prompts to ensure that the health technician and the recorder are performing the correct protocol with the correct data entry screen in the order the randomization process assigns.

Table 1 describes the randomizing schema for the 3 health technician-obtained WC measurements; and Table 2 provides a summary of the additional WC measurement protocols.

As table 2 shows a total of 4 additional WC measurements taken along with the NHANES WC that is already a part of the current MEC body measurements.

Table 1. Randomization order for the additional WC measurements to be done by health technician

Order	Randomization
1	ABC
2	ACB
3	BAC
4	BCA
5	CAB
6	CBA

Note: A=NHANES–WC
 B=WHO–WC
 C=MESA–WC

Table 2. Waist circumference measurement protocols for participants aged 20 and over

Protocol	Measurement	Anatomical landmark	Clothing	Tape used	Status	Exam room
MESA-WC	Self-HT coached	At the level of the umbilicus	Street ¹	Gulick	New	TBD
MESA-WC	Health technician	At the level of the	MEC	Gulick ²	New	Anthropometry

MESA-WC	Health technician	umbilicus At the level of the umbilicus	MEC	Lufkin ²	New	Anthropometry
WHO-WC	Health technician	At the mid-point between the highest point of the iliac crest and the lowest rib	MEC	Lufkin	New	Anthropometry
NHANES-WC	Health technician	At the level of the iliac crest	MEC	Lufkin	Measured since NHANES III	Anthropometry

Note:

1. A caliper will be used to measure the thickness (in millimeters) of street clothes on participants.
2. Lufkin & Gulick order will be randomized.

3. Explanation of any payment or gift to respondents.

Participants in the Comparisons of Waist Circumference Measurements Pilot Study will not receive any additional remuneration.

4. Estimates of Annualized Burden Hours and Cost.

The NHANES Comparisons of waist circumference measurements pilot study is budgeted for 15 minutes (See Table 1). Individuals age 20 and older who are also participants in the NHANES body measurements component will be eligible. The maximum number of respondents would be 530 (ages 20+) and the maximum burden 133 hours (530 respondents *15/60 hour = 133 hours – rounded up).

The burden hours for this feasibility study are captured in the “special studies” line of the currently approved NHANES OMB package. This study does not require any additional burden hours.

TABLE 3 – ANNUALIZED BURDEN HOURS AND COSTS

Type of Respondent	Form	Number of Respondents	Number of Responses per respondent	Average Burden per Response (in hours)	Total Burden Hours
Individuals in					

households	Comparisons of waist circumference measurements Pilot Study Adults Form	530	1	15/60	133
Total					133

5. Explanation for Program Changes and Adjustments.

The burden hours for this pilot study are captured in the “special studies” line of the currently approved NHANES OMB package. This study does not require any additional burden hours.

List of attachments:

- A. ATT A - Comparisons of Waist Circumference Measurements Pilot