Audiometry

Public Health Objectives:
Hearing loss, severe enough to interfere with speech, is experienced by approximately eight percent of U.S. adults. Hearing loss at this level has consequences for quality of life, as well as other problems. NIDCD, which sponsors the NHANES Audiometry Component, wants to change the Audiometry Examination target age for 2011–2012 to the 20–69 year age group, which was studied previously in 1999–2004. This will provide follow up data on trends in adult hearing loss over time. There are also several other additions and/or modifications to AUQ data collection. These include adding the previously validated Gallaudet Self-Rating Scale for hearing (to provide for the first time, data on functional hearing ability and to provide updated validation of the question set); perform follow up analysis of tinnitus in the U.S. adult population; and to update U.S. population data for noise-induced hearing loss in adults.

Staff:
Medical technician

Protocol:
The hearing component for NHANES will test a full-sample of adults ages 20–69 years using pure tone audiometry and tympanometry. Pure tone audiometry thresholds will be obtained in both ears at 500, 1000, 2000, 3000, 4000, 6000, and 8000 hz. To detect middle ear disease, tympanometry will be conducted to provide an estimate of tympanic membrane compliance. The otoscopic exam will examine the outer ear to identify abnormalities, which may require alternate audiometric procedures or influence the results obtained.

Time Allotment:
16 minutes

Health Measures:
- Evaluation of hearing sensitivity;
- Evaluation of the physiological function of the middle ear; and
- Physical examination of the outer ear.

Eligibility:
Participants ages 20–69 years

Exclusion Criteria:
Inability to remove a hearing aid. Otherwise there are no precluding conditions for otoscopy, immittance, or audiometry.

Justification for Using Vulnerable Populations:
There is no reason to exclude mentally impaired or handicapped individuals because there is no contraindication if they can understand exam instructions.

Risks:
There are no known risks with the hearing examination.

Report of Findings:
MEC
Level 1: None
Level 2: None
Level 3: Classification of hearing ability based on pure-tone audiometry

Text as it appears in the preliminary and final report:

The softest sounds you are able to hear are called hearing thresholds. Your thresholds at different frequencies (pitches) are reported in the table below. The lower pitched sounds are towards the left of the table and the higher pitched sounds are toward the right. Values of 25 dB or less are considered normal hearing.

Hearing Levels by Ear and Frequency (Air Conduction)

	Frequency (Hz)						
	500	1000	2000	3000	4000	6000	8000
Right Ear	999	999	999	999	999	999	999
Left Ear	999	999	999	999	999	999	999

Thresholds reported in dB HL

Your hearing was tested by a trained examiner. Screening results using an automated audiometer <*insert normal hearing text* ***or*** *text from* **Attachment 40 – Audiometry Report**> in your right ear. In your left ear, results <*insert normal hearing text* ***or*** *text from audiometry table*>. <*Insert recommendation text below, if required*>

If any threshold in either ear exceeds 25 dB HL insert:

The audiometry test can identify a hearing problem but cannot determine the cause of hearing loss. We recommend that you see a doctor regarding your hearing loss if you have not already done so.

Body Composition—Dual-Energy X-Ray Absorptiometry (DXA)

Public Health Objectives:
The body composition component will consist of dual-energy X-ray absorptiometry (DXA) whole body scans. The whole body scans will provide information on lean mass, fat mass, and percent body fat, and distribution of body fat for participants 8–59 years of age.

Evaluation of body composition will provide:

- Nationally representative data on total and regional bone, lean mass, fat mass, and percent fat, overall and for age, gender, and racial/ethnic groups;

- Estimates of the prevalence of obesity, as distinct from overweight;

- Data to study the association between body composition and other health conditions and risk factors (i.e., cardiovascular disease, diabetes, hypertension, and activity and dietary patterns; and

- Distribution of body fat: android fat is associated with excess weight carried around the abdomen; gynoid fat is associated with extra weight around the hips and thighs. Android obesity is related to a higher risk than gynoid obesity for chronic diseases such as hypertension, type 2 diabetes, and heart disease.

Staff:
Health technician (MEC) with radiology certification

Protocol:
Dual-energy x-ray absorptiometry delivers a small amount of radiation through a scanning arm while the participant lies in the supine position.

Time Allotment:
Whole body scan time is 3 minutes; total allowed for the procedure is 9 minutes.

Health Measures:
1) Values will be obtained for the total body and for each arm, each leg, the trunk, and head:
   - Total body tissue (gm)
   - Bone mineral content (gm)
   - Bone area (cm^2)
   - Bone mineral density (gm/cm^2)
   - Fat content (gm)
   - Lean mass (gm)
   - Lean mass plus bone mineral content (gm)
   - Percent fat (%)
2) Distribution of body fat (android\gynoid ratio)

Eligibility:
8–59 years

Safety\Exclusion Criteria:

- Pregnancy;
- X-rays or scans in the past seven days that used contrast material such as dyes or barium; and
- Weight over 450 pounds and height over 6'5" (limitations for examination table).

Risks:

Minimal risk. The total radiation dose is extremely low, 0.01 to 0.04 mrem per scan, which is within the range of background radiation and considerably less than conventional X-rays. A chest X-ray, for example, delivers a radiation dose of 40 mrem.

Justification for Using Vulnerable Populations:

- Minors under 18 are included in the DXA assessment to obtain information on critical periods for bone accretion;
- Pregnant women will be excluded from DXA because of the radiation exposure, however minimal; and
- Mentally impaired individuals will not be excluded from body composition because there is no contraindication.

Report of Findings:

MEC None
Level 1: None
Level 2: None
Level 3: Percentage body fat

Total percentage body fat (ages 8–59) will be reported in the final report of findings sent to participants from NCHS.

Variables Reported*:*

Percentage total body fat (participants 8–59 years)

Text as it appears in the final report:

Heading: Body scan

Introductory paragraph for body fat:
The whole body scan provides information on your percent body fat.

If SP is 8–59 years of age:

> The body composition exam results showed that your total body fat is ____%.

We do not know exactly what percent body fat is considered healthy for your age and gender. Researchers are working to define the healthy ranges for the public. You may want to discuss this result and your body measurement findings (page 1) with your doctor to find out what they mean for you. Too much body fat can increase a person's risk of getting diabetes or heart disease.

Else:
Participants under 8 years of age or 60 years and older did not have a whole body scan.

Body Measurements—Anthropometry

Public Health Objectives:

The objectives of the body measurements component (also called the anthropometry component) are to provide nationally representative body measures data to: 1) estimate the prevalence of overweight and obesity in the U.S. population; 2) study the association between body measures and body composition; 3) study associations between weight and body measures and health conditions and health risk factors such as cardiovascular disease, diabetes, hypertension, physical inactivity, and dietary patterns; and 4) monitor growth and development in children and adolescents. The NHANES body measures data are used in conjunction with many other NHANES examination, interview, and laboratory data.

Overweight is a major public health problem in the United States. The recent increases in overweight and obesity prevalence in the U.S. population have been called an epidemic. NHANES is unique in collecting nationally representative measured data on body measures and composition. Body measures data from NHANES are used to provide national reference data for the U.S. population, including race/ethnic subpopulations, to set and evaluate progress toward achieving national health objectives, and to monitor trends over time. NHANES body measurement data have been collected using standardized methods since the first National Health Examination Survey (1960–1962).

Staff:

- Health technician
- Recorder

The recorder assists with positioning during the exam (particularly for young children) and records the body measures values during the examination.

Protocol:

Weight:

The participant stands on a floor scale that is equipped with a digital read-out. For young children, a parent or guardian holds the child for the body weight measurement. The scale is "tared" or set to zero with the parent on the scale; the child is handed to the parent and the weight of the child is measured. All body weight data are captured electronically and are automatically entered into the NHANES database.

Stature and Recumbent Length:

Height and recumbent length are measured using a wall-mounted or fixed stadiometer and infantometer, respectively. The stadiometer and infantometer devices are connected to an automated data electronic database; stature and length data are entered into the NHANES database automatically.

Head Circumference:

A flexible, plastic, head circumference, measurement tape is used to measure the head circumference of infants.

Lengths (upper arm and upper leg) and Circumferences (mid-arm, and waist):

All measurements are made using a steel measuring tape.

Sagittal Abdominal Diameter Measurement:
The supine sagittal abdominal diameter is measured using the Holtain-Kahn Abdominal caliper.

Time Allotment:
7–8 minutes

Target Sample Age Groups for the NHANES Body Measurement Assessments:

- Body Weight: all ages
- Recumbent length: 0 through 47 months
- Standing height: 24+ months
- Upper leg length: 24+ months
- Upper arm length: 2+ months
- Head circumference: 0 through 6 months
- Mid-upper arm circumference: 2+ months
- Waist circumference: 24+ months
- Sagittal abdominal diameter: 8+ years

Eligibility:
All sample persons. Refer to the Target Sample Age Groups.

Exclusion Criteria:
Pregnant women and persons over 600 pounds are excluded from sagittal abdominal diameter measurement.

Justification for Using Vulnerable Populations:

- Minors are included in this component because they are an important target population group. Body composition findings are linked to other household interview and health component data and are used to track changes that occur in health over time.
- There is no reason to exclude mentally impaired or handicapped individuals because there is no contraindication if they can understand exam instructions.

Risks:
None

Report of Findings:
MEC
Level 1: None
Level 2: None
Level 3: Height, weight, BMI, and waist circumference

For non-pregnant persons 20 years and over. ***Text as it appears in the preliminary and final report:***

Based on your height, your weight is _____.

Body mass index	Statement
< 18.5	**below the range of a healthy weight, and you may be underweight.**
18.5 – < 25.0	**within the range of a healthy weight.**
≥ 25.0 – < 30.0	**above the range of a healthy weight, and you may be overweight.**
≥ 30.0	**above the range of a healthy weight, and you may be obese.**

For non-pregnant minors ≥ 2 or < 20 years of age. ***Text as it appears in the preliminary and final report:***
Based on your child's age, gender and height, {his/her} weight is _____.

Body mass index	Statement
< 5th percentile*	**below the range of a healthy weight, and {he/she} may be underweight.**
≥ 5th percentile < 85th*	**within the range of a healthy weight.**
≥ 85th percentile < 95th*	**above the range of a healthy weight, and {he/she} may be overweight.**
≥ 95th percentile*	**above the range of a healthy weight, and {he/she} may be obese.**

*Based on the 2000 NCHS BMI-for-age growth chart curves for boys and girls

Waist circumference statement:
The waist circumference statement is not printed if: 1) the participant is under 20 years of age, 2) the BMI is < 18.5, or 3) the participant is pregnant.

Gender	Statement
If male	For men, a waist circumference greater than 40 inches is associated with an increased risk of health problems such as type 2 diabetes, high blood pressure, and cardiovascular disease. This is based on guidelines from the National Heart, Lung and Blood Institute, NIH, 1998.
If female	For women, a waist circumference greater than 35 inches is associated with an increased risk of health problems such as type 2 diabetes, high blood pressure, and cardiovascular disease. This is based on guidelines from the National Heart, Lung and Blood Institute, NIH, 1998.

Dietary Interview Component

Includes 24-Hour Dietary Recall Interview and Post-Recall Questionnaires

Public Health Objectives:
Dietary factors are associated with 5 of the 10 leading causes of death in the U.S. population. NHANES is the cornerstone of the National Nutrition Monitoring and Related Research Program (NNMRRP). Policy makers and researchers require NHANES dietary data to assess the quality and adequacy of the U.S. diet in relation to health parameters, to evaluate the impact of program changes including welfare reform, legislation, food fortification policy, and child nutrition programs, and to identify target groups for public health education and awareness programs. Dietary practices and behaviors are used to evaluate the adoption of the *Dietary Guidelines for Americans* and *Five-a-Day Program* recommendations.

The objective of the component is to estimate total intake of food energy (calories), nutrients, and non-nutrient food components from foods and beverages that were consumed during the 24-hour period prior to the interview (midnight to midnight). Following the dietary recall, a short questionnaire will be administered to ascertain whether the person's intake on the previous day was usual or unusual, the source of tap water consumed, use of salt, special diet use, and frequency of fish and shellfish consumptions during the past 30 days. Subsamples of examinees will be asked questions about recent health (1–11 year olds), and recent pesticide exposure (6–7 year olds). These questions are included in **Instruments – Post Recall Questions.**

Staff:
Dietary interviewer

Protocol:
All NHANES examinees are eligible for the dietary interview component. A computer-assisted dietary interview software program was developed for use in the survey. The dietary interviewer records detailed information about the foods and beverages reported. Instructions will be provided to the respondent orally in English and/or Spanish. Measurement aids and visuals including charts and drawings will be used by the respondent to quantify the foods and beverages that are reported. Data files are transmitted electronically to a coding center located offsite.

A telephone follow-up dietary interview will be scheduled 4–11 days after their MEC exam for all the examinees. A set of measuring guides (including a USDA food model booklet, a ruler, a set of household spoons, and a set of measuring cups and measuring spoons), an appointment reminder card with the date and time of the scheduled interview, and a phone contact number will be given to the participants at the end of their MEC dietary interview. The phone follow-up interview will be conducted using the same dietary interview system as used in the MEC and will be made from a telephone center located offsite.

The interviewers will perform data retrieval by telephone when the information provided by the respondent or a proxy is incomplete; the interviewers will obtain permission from the SP or proxy to conduct data retrieval.

Each week, dietary interviewers are asked to audiotape an interview and send it back to the home office for review (approximately 5% of each interviewer's work). The date and session of the taped interview are randomly selected and communicated to the interviewers via email. Home office staffs will review the audio tape to monitor the quality of the interview and provide written feedback to the interviewer. Prior to the taping, interviewers will ask permission and obtain a written informed consent **(Attachment 41 – Permission to Audiotape the Dietary Interview)** from the SP. If the SP is 17 years or younger, a parental consent will also be obtained. A verbal permission will also be recorded in the audio-tape once the taping begins. At the end of the taping, permission for keeping the audiotape will be obtained from the SP. If the SP chooses not to allow the audiotape to be kept, the audiotape will be immediately destroyed in the presence of the SP. All audiotapes will be erased after the quality control review process has been completed by survey staff.

Time Allotment:
Depending on the types and numbers of foods reported in the dietary recall, the length of the interview ranges from 15–30 minutes per interview.

Health Measures:
Not applicable

Eligibility:
All survey participants are eligible for the dietary interview component. Translators may assist respondents when needed; and proxy reporting is permitted.

Exclusion Criteria:
The only circumstances that would lead to exclusion would be in instances when communication or cognitive difficulties make it impossible for the participant to provide the necessary information, and a proxy reporter is not available to complete the interview.

Justification for Using Vulnerable Populations:

- Minors are included in this component because they are an important target population group. Dietary data are linked to other household interview and health component data and are used to track changes that occur in food and nutrient intakes over time.

There is no reason to exclude mentally impaired or handicapped individuals because there is no contraindication.

Risks:
There is no greater than minimal risk associated with this component.

Report of Findings:
No findings are reported to respondents.

MEC Interview

Public Health Objectives:

Questionnaire data to support the analysis of the examination data are collected both in the household and MEC interviews. Questions about medical history and health behaviors asked during the household interview are often administered in the presence of other household or family members. The MEC interview offers the opportunity to obtain information about personal medical conditions and health behaviors in a private setting. Each week, MEC interviewers are asked to audiotape an interview **(Attachment 42 – Permission to Audiotape MEC Interview)** and send it back to the home office for review (approximately 5% of each interviewer's work). The date and session of the taped interview are randomly selected and communicated to the interviewers. Home office staffs will review the audio tape to monitor the quality of the interview and provide written feedback to the interviewer. Prior to the taping, interviewers will ask permission and obtain a written informed consent from the SP. If the SP is 17 years or younger, a parental consent will also be obtained. A verbal permission will also be recorded in the audio-tape once the taping begins. At the end of the taping, permission for keeping the audiotape will be obtained from the SP. If the SP chooses not to allow the audiotape to be kept, the audiotape will be immediately destroyed in the presence of the SP. All audiotapes will be erased after the quality control review process has been completed by survey staff.

Generally, the questions asked in the MEC private interview are more sensitive in nature than questions asked during the household interview. Two modes are used for question administration—face-to-face and a self-interview. The most personal questions, on topics such as drug use and sexual behaviors, are administered in the absence of an interviewer and using audio computer-assisted self-interview (ACASI) technology. With ACASI, questions are heard through earphones and responses are entered into the computer directly via touch screen. Additional questions, such as recent exposure to environmental chemicals and current health conditions, are asked during the MEC interview simply because it is the most convenient venue to administering additional questions.

Protocol:

Face-to-face interviews:

Using the computer-assisted personal interview (CAPI) technology, an interviewer administers questions in a private room with only the survey participant present. Administration time is roughly 10–25 minutes, depending on age. All questions can be administered in English and Spanish, and a portion of the questions can be administered with an interpreter and/or proxy interviewer. Descriptions of the sensitive sections of the MEC Interviewer are described in the background section below.

- Pesticide Use (6+ years)
- Volatile Organic Compounds (20+ years)
- Current Health Status (12+ years)
- Depression Screener (12+ years)
- Reproductive Health (12+ years)
- Muscle Pain and Injury (12+ years)
- Physical Activity (12–15 years)

- Weight History and self-image (8–15 years)
- Alcohol Use (18+ years)
- Recent tobacco use (20+ years)
- Urologic Conditions (20+ years)
- Cognitive Functioning (60+ years)

Depression Screener:
Depression is a debilitating condition and may result in reduced worker productivity, increased use of sick leave, and increased health care utilization. Depression is a risk factor for coronary heart disease and is a risk factor for institutionalization, especially among the elderly. The U.S. Preventive Services Task Force recently concluded that there is sufficient evidence to recommend periodic screening for depression. The goal of this section will be to understand the co-morbidity of depression and other chronic diseases including cardiovascular disease, diabetes, and obesity and to investigate other health risk factors related to depression in adolescents and adults.

Depression will be assessed using the Patient Health Questionnaire (PHQ-9). This screening instrument has been validated against independent structured diagnostic interviews in both clinical and general population studies, and serves both as a depression severity measure as well as a diagnostic instrument for the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV) depressive disorders. The PHQ-9 refers to the previous 2-week interval and consists of nine items of depression symptoms plus a question on functional impairment. If respondents report thoughts about suicide, the interviewer will refer them to the MEC physician prior to leaving the examination center. **(Attachment 43 – Referral Protocol - Suicide)**

Reproductive Health and History:
Age at menarche, pregnancy history, history of breast feeding, hysterectomy and oophorectomy, menopausal status and symptoms of menopause, and use of exogenous hormones (oral contraceptives and hormone replacement therapy are obtained. Most of the data collected in this questionnaire section will be used as covariates for other analyses.

Muscle Pain and Injury:
To make the Creatine Phosphokinase (CPK) laboratory data more useful, a short series of questions administered during the MEC interview has been added on muscle pain and injury. Recent muscle injury or strenuous exercise can elevate the CPK. The data from the CPK questionnaire will be used to develop exclusion criteria for the population based study of CPK, so that national reference ranges can be created that are as representative as possible of the normal, healthy U.S. population. The data will also be used for analytical studies, particularly screening the potential for certain high risk prescription drugs, such as the statins, to cause muscle injury.

Weight History and Self-Image:
Youths will answer questions by themselves about weight loss, the reasons for weight loss and the types of weight loss practices used. They are also asked about body image. The prevalence of overweight adolescents has nearly tripled in the past two decades. High cholesterol and high blood pressure, risk factors for heart disease, occur with increased frequency in overweight

children and adolescents compared to children with a healthy weight. Children and adolescents are especially prone to fad diets and eating disorders. Unhealthy methods of weight loss can compromise growth and are not recommended by health care professionals. Before NHANES included these questions, national data on the reasons children and adolescents try to lose weight or the methods they employ to lose weight were unavailable.

Cognitive Functioning:
Cognitive functioning of older adults is an important risk factor for loss of independence, institutionalization and mortality. Its inclusion in NHANES provides the ability to investigate prevalence and co-morbidities of declining cognitive functioning with other self-reported and objective physical measurement.

Participants ages 60 years and older are administered three standardized tests of cognitive functioning. Tests are administered in English and Spanish by the interviewer as well as in Korean, Chinese and Vietnamese with the assistance of an interpreter. The first, the Consortium to Establish a Registry for Alzheimer's Disease Word List Learning Test (CERAD), assesses recall and memory. For this test, the respondent is asked to read aloud 10 words, one at a time, displayed on the computer screen, and then he/she is asked to recall as many of the words as possible within 90 seconds. There are three consecutive word reading, word recall trials, and a final recall that occurs after the other two cognitive functioning tests are administered. The Animal fluency Test, administered next, is designed to assess categorical verbal fluency, component of executive function. The respondent is asked to name as many animals as possible in 60 seconds. The third test, the Wechsler Adult Intelligence Scale (WAIS-III) digit symbol coding subtest, evaluates attention and processing speed. Participants are given 120 seconds to substitute, in writing, a symbol for a random succession of numbers ranging between one and nine. This test was previously used in NHANES III and the 1999–2002 NHANES in the household interview. If a respondent is unable to do either of the required pre-tests before beginning the Animal Fluency or the WAIS III digit symbol coding subtest, then the interviewer will refer him/her to the MEC physician prior to leaving the examination center.

Self-Interview:
After the face-face interview, the MEC interviewer will instruct the respondent on the use of the audio computer-assisted self-interview (ACASI). The interview is available in English and Spanish for all assigned age groups and in Korean, Chinese and Vietnamese for questions assigned to adults 18 years and older. The respondent is left alone in the room to complete the interview using a touch screen computer. Administration time varies (10–20 minutes) and is dependent on respondent age. Due to the private nature of these questions, no proxy interviews will be conducted for this component. The questionnaire includes the following sections:

- Alcohol (12–17 years);
- Drug Use (12–59 years);
- Sexual Behavior (14–59 years);
- Recent tobacco use and smoking history (12–19 years); and
- Pubertal maturation self-assessment (8–19 years).

Alcohol Use:

Alcohol consumption contributes significantly to the cause, course, and outcome of a multitude of physical, psychological, behavioral, nutritional, and social problems. Alcohol also impacts overall quality of diet and nutrient intake, especially energy (calories). The alcohol questions are brief, and the data from this section will be used primarily as covariates with other examination data analyses.

Drug Use:
The drug use questions focus on lifetime use of street drugs or recreational drugs and the intravenous use of these drugs. This section collects information on specific drugs including methamphetamine, heroine, and steroids, as well as marijuana use for all ages. Additional questions on age of initiation of drug injection, duration of injection drug use, and lifetime history of drug treatment are included. No measurements for the presence of drug metabolites will be conducted. The use of drugs has been demonstrated to be a risk factor for sexually transmitted diseases. Injection drug use is also a risk factor for blood borne pathogens, such as HIV, HBV and HCV. Information on drug use along with sexual behavior questions is necessary to develop a profile of risk-taking behavior.

Sexual Behavior:
Respondents are asked about age of first intercourse, number of sexual partners, use of condoms, and history of sexually-transmitted diseases. Information on sexual behavior is key to reducing the risk of STDs, including acquired immunodeficiency syndrome (AIDS).

The questions on sexual behavior are included to provide for the following: targeting risk reduction efforts; assessing the results of such efforts; and improving current understanding of the epidemiology of STDs. NHANES is designed to provide measures of both STD risks and sexually transmitted infection for the general population since the NHANES survey combines laboratory measures of STDs with behavioral data for both men and women for the full reproductive age range. These data can be used to estimate the prevalence of STD risk behaviors among major demographic subgroups of the U.S. population, to determine trends in the prevalence of STD risk behaviors, and to determine how risk behaviors for STDs influence the frequency of these infections.

Pubertal Maturation Self-Assessment:
The addition of the pubertal maturation self-assessment questions has important public health relevance, and will improve the utility of NHANES clinical data, biomarker data, and questionnaire data. Endocrine changes manifested in secondary sexual characteristics underlie many physiological changes during puberty. Sexual development correlates more closely with physical changes such as height, weight, bone density and certain biochemical markers than chronological age, thus facilitating assessment of bone health, and body composition in pre-adolescence and adolescence. Furthermore, early sexual maturity has been found to closely correlate with self-image and sexual behaviors, which are also assessed in the MEC interview.

In the pubertal maturation self-assessment module, high quality drawings of the Tanner stages are accompanied by text descriptions that include anatomical and technical terms. Visual enhancements, such as highlights, shading, and circles, help respondents focus on areas of interest. Girls are asked to select one breast drawing and one pubic hair drawing that look the

most like their bodies; and boys are asked to select one genital drawing and one pubic hair drawing that look the most like their bodies. The numbers of drawings presented to respondents varies by age. Youths, ages 8–9 years, select from drawings of Tanner stages 1 through 4, and youths ages 10–18 years select from drawings of Tanner stages 1 through 5.

Exclusion Criteria:
If the face-to-face interview was done by proxy there will not be an ACASI interview for the participant. Vision impairment can be a reason for exclusion for the ACASI interview, if the participant cannot see the screen.

Justification for Using Vulnerable Populations:
Mentally impaired individuals are included in the face-to-face interview when a proxy is available to answer.

Risks:
The interview presents no greater than minimal risk to subjects.

Report of Findings:
None

Muscle Strength

Public Health Objectives:
In October 2008, the federal government issued its first-ever Physical Activity Guidelines for Americans to provide science-based guidance on the types and amounts of physical activity that provide substantial health benefits for Americans. The Guidelines recommend that adults complete muscle strengthening activities in conjunction with general recommendations to obtain 150 minutes or more of physical activity. Similar guidelines exist for school-aged children. Muscle strength refers to the maximum force that can be generated by a specific muscle or muscle group. Recent studies indicate that higher muscular strength was significantly and inversely associated with overall mortality rates and morbidity and mortality due to various chronic diseases. These associations have been demonstrated to be independent from other major risk factors and cardiorespiratory fitness.

The NHANES muscle strength component is developed in collaboration with the National Cancer Institute (NCI). The goals of this component are to provide: 1) nationally representative data on muscle strength; 2) prevalence estimates of persons with poor muscle strength; and 3) data to study the association between muscle strength and other health conditions and risk factors, such as obesity, cardiovascular disease, diabetes, hypertension, and activity and dietary patterns.

Staff:
Health technician

Protocol:
Methods
The protocol is an isometric grip strength test using a handgrip dynamometer. The participant is asked to squeeze the dynamometer as hard as possible with each of his/her hands in a standing position. Each hand is tested three times, alternating hands between trials.

Time Allotment:
8 minutes

Health Measures:
Grip strength, as recorded by the dynamometer is recorded in kilograms (kg) to one digit after the decimal point.

A derived variable is created for combined grip strength, which is the sum of the largest reading from each hand. The combined grip strength variable is used for the Report of Findings. Kilograms is converted to pounds (lbs) for the Report of Findings.

Eligibility:
Sample persons aged six years and older who do not meet any of the exclusion criteria

Exclusion Criteria:
Participants are excluded from this component if they are unable to hold the dynamometer with both hands (e.g., missing both arms, hands, or thumbs on both hands, or paralysis of both hands).

Participants who are able to grip the dynamometer with one hand will still perform the component. Participants who had surgery on either hand or wrist in the last three months will not be tested on that particular hand.

Justification for Using Vulnerable Populations:
There is no reason to exclude mentally impaired persons, handicapped individuals or pregnant women from the grip test. Participants who cannot perform the test in standing position (e.g., wheelchair-bound, injured leg, etc) will be tested in sitting position.

Risks:
There is no more than minimal risk associated with the grip test.

Report of Findings:
A report of finding is provided to the participants at the end of the MEC exam. Texts in the report are different by age groups:

For 6 years olds:
Your grip strength measured by a dynamometer was ____ lbs. Researchers are still trying to learn more about muscle strength in your age group. Data collected in our survey, including your participation today, will help us to better understand this topic.

For 7–11 years old:
Your grip strength measured by a dynamometer was ____ lbs. Compared with other people of your age and sex, your muscle strength level is _____. (above average, average, or below average).

The classification is based on reference data from the Canada Fitness Survey Longitudinal Study.

[For those with results as "below average", include following additional texts in the report]
These test results are just for your personal information. They cannot be used to diagnose any disease. The results depend on how you did today, and on your level of physical fitness. Sometimes reduced hand muscle strength may be caused by pain or arthritis in the hands or other health problems.

For 12–14 years old:
Your grip strength measured by a dynamometer was ____ lbs. Compared with other people of your age and sex, your muscle strength level is _____. (above average, average, or below average).

The classification is based on reference data from the Canada Fitness Survey Longitudinal Study.
[For those with results as "below average", include following additional texts in the report]
These test results are just for your personal information. They cannot be used to diagnose any disease. The results depend on how you did today, and on your level of physical fitness. Sometimes reduced hand muscle strength may be caused by pain or arthritis in the hands or other health problems.

For 15–69 years old:
Your grip strength measured by a dynamometer was ____ lbs. Compared with other people of your age and sex, your muscle strength level is _____. (excellent, very good, good, fair, or poor)."
The classification is based on reference data from the Canadian Physical Activity, Fitness and Lifestyle Approach (CPAFLA).

[For those with results as "poor", include following additional texts in the report]
These test results are just for your personal information. They cannot be used to diagnose any disease. The results depend on how you did today, and on your level of physical fitness. Sometimes reduced hand muscle strength may be caused by pain or arthritis in the hands or other health problems.

For 70 years and older:
"Your grip strength measured by a dynamometer was ____ lbs. This is the first time that grip strength for people 70 years and older is being studied in a national survey in the US. We are using this information to learn about muscle strength in your age group."

For participants who only have completed data on one hand:
"Your grip strength measured by a dynamometer on your (right/left) hand was ____ lbs. Data collected in our survey, including your participation today, will help researchers to better understand this topic."

Oral Health

Public Health Objectives:
NHANES is critical for monitoring oral health status, risk factors for disease, and access to preventive and treatment services. This component will address public health significance in areas of surveillance, prevention, health promotion/disease prevention, health policy, evaluation of Federal health programs, standardization of new methods, and health and nutrition status of minorities and underserved populations. The oral health exam will collect information on tooth loss, dental sealants, dental fluorosis, dental caries, and periodontal disease.

Oral health data from NHANES will be used for the following:

- Assessing the prevalence of major oral health diseases and conditions including dental caries, edentulism, and periodontal disease;
- Assessing dental caries prevention efforts;
- Evaluating specific public health programs/new policies and initiatives;
- Targeting minority/underserved populations for monitoring of health status; and
- Evaluating Healthy People 2010 objectives related to oral health.

Staff:

- Dentist
- Dental recorder (Health technician)

Protocol:
The oral health exam consists of a visual/tactile examination with a limited questionnaire. The assessments are conducted using a dental explorer, periodontal probe, and dental mirror.

Time Allotment:
Depending on age, 2–10 minutes

Health Measures and Eligibility:
Sample participants ages one year and older are eligible for one or more parts of the exam. The following oral health subcomponents for the examination (with the age groups of interest in parentheses) are as follows:

- Medical History Screening (30 years and older);
- Tooth Count (1 year and older);
- Dental Caries (1 year and older);
- Dental Sealants (3–19 years);
- Dental Fluorosis Assessment (6–19 years);
- Periodontal Exam (30 years and older); and
- Miscellaneous/Report of Findings (1 year and older).

Exclusion Criteria:
All adults aged 30 years and older will be excluded from the periodontal examination if a positive response to any one of these four questions is given:

- Have you had a heart transplant?
- Do you have an artificial heart valve?

- Have you had heart disease since birth?
- Have you had a bacterial infection of the heart, also called Bacterial Endocarditis?

Justification for Using Vulnerable Populations:
Minors are included in this component because they are an important target population group. Oral health findings are linked to other household interview and health component data and are used to track changes that occur in health over time.
There is no reason to exclude mentally impaired or handicapped individuals because there is no contraindication.

Risks:
Minimal risk—including possible discomfort. There will be no exposure to radiation (no x-rays) or hazardous material (e.g., mercury), and no use of anesthetic agents.

Special Precautions:
None

Report of Findings:
All participants will receive general results about oral health assessment. The results will be provided in the Preliminary Report of Findings and in the Final Report of Findings.

The dental examination of the National Health and Nutrition Examination Survey is not, and is not intended to be, a substitute for the examination usually given to persons seeking care from their own dentists.

Neither a dental history nor x-rays are taken, and therefore the findings are solely the result of what can be seen at the time of the examination.

There are four levels of referral from the MEC and these levels are determined by the examining dentist:

- Level 1 - SP should see a dentist immediately;
- Level 2 - SP should see a dentist within the next 2 weeks;
- Level 3 - SP should see a dentist at his/her earliest convenience; and
- Level 4 - SP should continue with his/her regular routine dental care.

Physician Exam

Public Health Objectives:
High blood pressure is a marker for the chronic condition hypertension, which is a major risk factor for premature cardiovascular, cerebrovascular, renovascular and other vascular diseases. Standardized blood pressure measurements will be used to monitor prevalence of hypertension.

Staff:
Licensed physician

Protocol:
Pulse: the examining physician will determine a 30 second resting pulse rate.
Blood pressure: three systolic/diastolic BP measurements will be taken following a strict protocol. The average of the last two measurements is reported to the participant.

Pre-test counseling for STD/HIV testing: Physician will discuss the STD/HIV testing and assure the confidentiality of information collected. Physician will explain to the participants how they are to get their test results and will ask them to provide a password to be used to get results over the phone. Physician will answer any questions the participants may have about the STD or HIV testing.

Explain the self-administered vaginal swab HPV collection to females 14–59 years of age and give instructions on how to collect the sample.

During the physician exam, if signs of child abuse are found, the physician will report it to the local department of social services and the police. **(Attachment 44 – Federal Law on Child Abuse Reporting and Attachment 45 – OGC Brief re: Reporting of Child Abuse)**

Time Allotment:
Depends on age, the exam ranges from 2–13 minutes.

Health Measures:
Blood pressure

- Pulse (bpm)
- Systolic blood pressure (mmHg)
- Diastolic blood pressure (mmHg)

Eligibility:

- Pulse: 2 months and older
- Blood pressure: 8 years and older
- STD/HIV counseling: 14–59 years of age
- Vaginal swab collection: Females 14–59 years of age

Exclusion Criteria:

- Blood pressure—presence of the following on both arms: rashes, gauze dressings, casts, edema, paralysis, tubes, open sores or wounds, withered arms, a-v shunts, or if blood has been drawn from arm within last week.
- Largest cuff size does not fit around the arm
- STD/HIV testing—if the participant does not speak English, Spanish, Chinese, Korean or Vietnamese, no testing will be done.

Justification for Using Vulnerable Populations:
Minors are included in the pulse and blood pressure assessment because of the relevance and impact of high blood pressure in this age group. Mentally impaired individuals will be excluded from the STD/HIV unless a legally authorized representative is present.

Risks:
Minimal risk. Transient discomfort during blood pressure measurement.

Special Precautions:
None

Report of Findings:
MEC:
Pulse and Blood Pressure—Adult
Level 1: Systolic BP >= 210 and/or diastolic BP >= 120; Pulse > 140 bpm
Level 2: 120 < Systolic BP < 210 and/or 80 <=diastolic BP < 120
Level 3: Systolic < 120 and diastolic < 80

Text in Preliminary and Final Report of Findings is as follows:

Blood Pressure & Heart Rate

	Normal
Systolic bp_____ mm Hg	< 120
Diastolic bp ____ mm Hg	< 80

Resting pulse rate ____

Your blood pressure today is insert statement from table below

Systolic	**Diastolic**	**Finding**
< 120	< 80	**within the normal range***
120-130	80-89	**above normal and is in the prehypertensive range***
140-159	90-99	**high***
160-209	100-119	**very high***
≥210	≥120	**severely high**

*Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003

Blood Pressure - Children
Children between the ages of 8–17 years will have BP levels reported as follows:

Your child's blood pressure today is insert statements 1, 2, 3 or 4 from table below

Category	**Statement**
1	**within the normal range**
2	**in the prehypertensive range**
3	**high**
4	**very high**

Based on the Fourth Report of the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents. *Pediatrics* 2004; 114; 555-576

Numeric determination based on tables found here:
http://www.nhlbi.nih.gov/guidelines/hypertension/child_tbl.htm

Confidential reporting of STD/HIV test results:

- Toll free phone line for participant to call for results.

- Participants will be counseled by a health educator and referred for care if they have positive results for chlamydia, herpes simplex virus type 2, HIV or high-risk strains of human papillomavirus. List of STD/HIV treatment sites will be obtained in advance for each stand and be made available for participant. Negative results for chlamydia, herpes simplex type 2, HIV or high-risk strains of human papillomavirus are also provided.

Respiratory Health

Public Health Objectives:
This respiratory component will include an assessment of lung function testing, spirometry with and a measurement of exhaled nitric oxide (NO). Exhaled NO provides a measure of airway inflammation is a factor in the causal pathway of asthma and possibly other lung diseases. Data suggest there are large differences in exhaled NO between asthmatics and healthy controls; exhaled NO levels are 3 to 10 fold greater in asthmatics. These differences make the method sufficiently sensitive to detect cases of either mild asthma or incipient asthma, which are usually symptom-free. In addition, measurement of airway inflammation may reveal diseased airways not detectable by symptoms, clinical examination, questionnaire, baseline spirometry or bronchodilator studies.

Spirometric measurements of lung function, especially the Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV_1), and their ratio (the FEV1/FVC %) are important for characterization of asthma and obstructive airway disease both for clinical as well as epidemiological purposes. Youth and adults with airway obstruction detected by baseline pulmonary function testing undergo repeat spirometry after inhalation of a short-acting β_2-adrenergic bronchodilator. Bronchodilator reversibility spirometry testing is a standard clinical procedure and has been employed in many population-based surveys of asthma and COPD both in adults and children. Bronchodilator reversibility testing is used to distinguish more precisely between asthma and COPD and other causes of fixed obstructive lung disease, and is used to determine asthma severity and the degree of asthma treatment control. Assessment of respiratory health will allow improved estimation of asthma prevalence based on objective measurements and help analysts to discriminate asthmatics from otherwise healthy individuals who have episodes of wheezing.

Ages:
6–79 years

Time Allotment:
15–20 minutes

Protocol:
Spirometry
Spirometry will be performed the same way as in the 2009–2010 NHANES, and meets current American Thoracic Society (ATS) Guidelines for quality control. The participants are asked to complete and a minimum of three but no more than eight full single breath tests according to The tests consist of the participant inhaling deeply, and then exhaling forcefully through a tube connected to the spirometer. Adolescents and adults will be asked to exhale for a minimum of 6 seconds, children 6 to 10 years will be asked to exhale a minimum of 3 seconds. Testing will be performed routinely in a standing position, but if necessary participants will be allowed to sit.

At the completion of baseline spirometry, the participant's best spirometry results for FEV1/FVC% against 1) the lower limit of normal based on standardized reference prediction equations for children and adults, and 2) whether the participant's best FEV1/FEV% value is ≤ 70%. If either condition is met, the referred for bronchodilator testing. The MEC physician

explains the bronchodilator testing, assesses the participant for bronchodilator medical exclusion criteria, and then administers a short-acting inhaled prescription bronchodilator. The participant inhales one puff from the MDI, exhales, and then inhales another puff for a total of two doses. The medicine is given a minimum of 10 minutes to take effect, and then a repeat spirometry examination is conducted. The physician also obtains a separate consent **(Attachment 46 – Bronchodilator Consent)** from the participant to perform the bronchodilator part of the study.

Exclusions:
Baseline Spirometry
Medical exclusion included current chest pain or a physical problem with forceful expiration, using supplemental oxygen, recent surgery of the eye, chest or the abdomen; recent heart attack, stroke, tuberculosis exposure or coughed up blood. Adults with a personal history of detached retina or a collapsed lung and children with painful ear infections were also excluded

Bronchodilator Administration
Medical exclusion included cardiovascular conditions (uncontrolled blood pressure, irregular pulse on examination, taking medication for major arrhythmia, having an implanted defibrillator, or history of congenital heart disease) or taking certain prescription medications (a monamine oxidase inhibitor, an anticonvulsant, a tricyclic antidepressant plus current treatment for cardiac disease, potassium-lowering drugs). Examinees are also excluded from bronchodilator administration if they had already recently taken a β2-adrenergic bronchodilator, or had a previous adverse reaction to albuterol. Currently pregnant or women who are breastfeeding are also excluded.

Report of Findings:
Findings are sent to participants after the data are reviewed by NHANES spirometry consultants. Best values, predicted values, lower limits of normal, and percent predicted values for FVC, FEV1, FEV1/FVC%, Peakflow (L/sec), FEF25-75% (L/sec) are included in the findings.

Protocol:
Exhaled Nitric Oxide
Exhaled NO is measured using the Aerocrine NIOX MINO^{R}, a portable, hand-held NO analyzer (Aerocrine AB, Solna, Sweden) approved by the FDA in 2008. This device relies on an electrochemical sensor to detect exhaled NO levels and provides measurements of from 5 to 300 ppb. Briefly, the testing was conducted with participants sitting in front of a mirror. Holding the device, participants are asked to first empty their lungs, then to place their mouth on the disposable filter mouthpiece and to fill their lungs to capacity. Participants are then asked to blow out all of their air at a constant pressure. The NIOX MINO^{R} has a dynamic flow restrictor to stabilize flow rate at 50 ml/sec and provides auditory and visual cues to assist examinees in performing the test correctly. The standard exhalation time, as specified by the manufacturer, was 10 second for examinees who were at or above 130 cm tall, and 6 seconds for those below 130 cm. The NHANES protocol requires two reproducible exhalations in accordance with the testing procedures recommended by the American Thoracic Society and European Respiratory Society.

No more than four full, complete ENO test trials or a total of 10 attempts to complete a trial will be administered. ENO testing routinely takes approximately 10 minutes.

Exclusions:
Medical exclusion included current chest pain or a physical problem with forceful expiration, using supplemental oxygen.

Report of Findings:
The results are not reported. There is not a current scientific consensus or guidelines for interpreting clinically significant exhaled NO levels. Factors known to markedly influence exhaled NO levels such as tobacco use and recent upper respiratory infection.

Tuberculin Skin Test

Public Health Objectives:

To support public health programs in the control, prevention, and eventual elimination of tuberculosis (TB) in the United States, accurate and comprehensive data are needed about the extent of the TB burden in the community. National prevalence of TB was last measured in the 1999–2000 NHANES. Since 1992, the annual rate of new TB cases has been decreasing in the United States from 10.5 in 1992 to 4.8 in 2005. The 1999–2000 NHANES determined that 4.2% of the civilian, non-institutionalized population, or 11,213,000 people, had a latent TB infection. Prevalence of TB infection in males was higher than in females (5.2% in compared with 3.2%). Non-Hispanic blacks and Mexican-Americans had higher prevalence than non-Hispanic whites (7.0%, 9.4%, and 1.9 %, respectively).

To determine the current prevalence of TB infection, NHANES participants six years of age and older will receive two tests for *M. tuberculosis* infection: a skin test and a blood test. Participants will be asked questions regarding country of birth, occupation, prior TB tests, prior treatment for TB infection or TB disease, and prior exposure to TB. Data will be used to: 1) estimate the number and proportion of persons with TB infection in the U.S. population and in specific demographic subgroups; 2) estimate trends in TB infection in the U.S. population and in demographic and geographic subgroups; and 3) analyze demographic, geographic, socioeconomic, and other risk factors for TB infection.

Staff:

A phlebotomist, medical technologist or a physician will place the skin test. Certified phlebotomists will draw blood for the TB blood test. The skin test results will be read by six full-time skin test readers.

Protocol:

The TB skin test (TST) will be applied in the NHANES Mobile Examination Center (MEC), only if the participant did not refuse the blood draw or did not have a blood draw for any reason. The solution used is Tubersol (Connaught), a commercially marketed skin test that indirectly tests for antigens present in *M. tuberculosis*. Tubersol will be administered by the Mantoux method with intradermal injection of 0.1 mL of tuberculin into the volar surface of the forearm using a tuberculin syringe.

After administration of the TST, the participant will be appointed to either a home visit or Field Office visit in 46–76 hours to have the TST result read and recorded. A tuberculin reaction is a delayed-type hypersensitivity reaction, which if present, is measured in millimeters (mm) by documenting the measurement of the induration transverse to the long axis of the forearm. The measurement is done by trained readers who have completed training conducted by staff from CDC's Division of Tuberculosis Elimination (DTBE). The sensitivity and specificity of Tubersol is difficult to measure; however, data from one randomized clinical trial reported a sensitivity of Tubersol of 92%, and a specificity of 99.2% using a 10 mm cutoff. The participant will receive a **TB Skin Test Report of Findings (Attachment 47 – TB Skin Test Report of Findings).**

Laboratory Methods for the Blood Test for TB Infection:

NHANES will use the QuantiFERON®-TB test, approved by FDA as an aid in diagnosing infection and active TB. The result of the blood test will be provided to participants in the Final Report of Findings. If the TB blood test result is positive, the finding will be mailed to the participant (or parent/guardian of minors) by the Early Reporting system **(Attachment 31: Early Reporting Letter – Positive TB blood test result). The text for the Final Report of Findings is detailed in Attachment 32.**

Sensitivity and Specificity for QuantiFERON®-TB Test:
In general, the QuantiFERON®-TB test sensitivity is considered similar to the TST. Estimates of QuantiFERON®-TB test sensitivity have varied widely in published studies, which have involved predominantly adults with culture-confirmed active tuberculosis. QuantiFERON®-TB test is expected to be more specific than a TST because the antigens used in these tests are relatively specific to *M. tuberculosis* and should produce fewer false-positive tests (i.e., they should not produce cross-reactions after sensitization by BCG and most nontuberculous mycobacteria, such as *M. avium* complex).

Eligibility:
Participants aged 6 years old and over who do not meet the exclusion criteria are eligible for the survey and for testing for TB infection. If the participant refused phlebotomy, or did not have blood drawn for any reason, they will **not** have the TB skin test.

Exclusion Criteria:
Participants who have had a severe reaction to a TST, (i.e., anaphylactic shock or acute hypersensitivity reaction), or participant has severe skin condition, such as burns or active eczema over both arms will be excluded.

Justification for Using Vulnerable Populations:
Minors over the age of one year are included in this component because they are an important target population group. Tuberculin findings are linked to other household interview and health component data and are used to monitor trends for infection. Mentally impaired individuals will be included

Risks:
The TST is associated with minimal medical risk. Nonspecific irritation may develop at the TST site within 20 minutes of test placement and usually subsides within 24 hours. Some persons who have positive TST results also may have redness or itching at the site that may last for approximately 1 week. Adverse events such as anaphylactic shock or acute hypersensitivity reaction associated with skin testing antigens are very rare. Participants will be required to stay in the Mobile Examination Center for 15 minutes after TB skin test placement for observation. A system for collecting data on adverse events using TST will be in place. These will be summarized in annual NHANES continuation requests to the NCHS ERB.

Report of Findings:
Reported in the Field Office or Home

Level 1:	None
Level 2:	Induration > 10 mm in either arm will result in referral to community

physician or local health department.

Level 3/Routine: Report of findings

If a participant tested positive for HIV, the health educator will re-evaluate the participant's TB skin test result as part of the HIV counseling session. If an HIV participant had a TST of 5 mm or more, but under 10 mm, they will be referred for follow-up.

Vaginal Swab Collection

Public Health Objectives:
Human papillomavirus (HPV) infection is one of the most common sexually transmitted infections in the United States. Cervical infection with certain types of HPV is a major risk factor for cervical cancer in women. These types include HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68. NHANES has been measuring high risk HPV infection among females 14 years of age to 59 years of age since 2002.

Reducing the prevalence of HPV infection is a Developmental Healthy People 2020 objective. Detection and typing of HPV DNA in vaginal swabs (in conjunction with testing of NHANES sera for HPV 16 antibody) permits the evaluation of trends in prevalence of type-specific HPV infection by age, sexual behavior, and race/ethnicity. Two HPV vaccines are now available and have been approved for use in both girls and boys. Monitoring the national prevalence of HPV infection is critical for planning vaccination strategies in the United States.

Staff:
The MEC Physician will instruct females on how to do the self-administered vaginal swab.

Protocol:
Testing for HPV DNA will be done from vaginal fluids collected using vaginal swabs. Studies have demonstrated that recovery of HPV from self-collected swabs is comparable to that from physician collected cervical samples.

Female study participants aged 14–59 will be eligible for HPV testing using a self-administered vaginal swab. The MEC Physician will explain the soft foam vaginal swab collection technique to the study participant. After the physician goes through the written directions with the study participant, the study participant will be given the vaginal swab, a written set of directions, and directions to the bathroom. If the study participant is uncomfortable with this procedure, the physician will try to answer concerns and questions or use completion codes for refusal. A study coordinator will collect the self-administered swabs, log the study participant out of the room, escort her to the next component, and deliver specimens to the lab.

The vaginal swab will be tested for high-risk HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68. Physician counseling and instruction for vaginal swabs and written instructions for the participant can be found in the NHANES Physician examination Manual.

Time Allotment:
The length of time for providing instruction is three minutes. Collection of the swab is approximately 5–7 minutes.

Eligibility:
Females aged 14–59 are eligible for the survey. Women who are mentally impaired who are not accompanied by a guardian will not be eligible.

Exclusion Criteria:

A participant with communication or cognitive difficulties would be excluded from obtaining the self-administered swab.

Justification for Using Vulnerable Populations:
Minors are included because they are an important target population. Mentally impaired persons (accompanied by a guardian) are important to include for a complete understanding of HPV infection in the population. If the physician determines the mentally impaired person will not be able to administer the swab alone in the bathroom, she will be excluded.

Risks:
There are minimal risks associated with this component.

Report of Findings:
HPV will be reported to females tested. See section on STD/HIV reporting in the **Reporting Examination Findings.**