Mobile Exam Center Components Descriptions

The following pages describe the exam components as offered in the Mobile Examination Center.

Audiometry

Public Health Objectives:

Hearing loss severe enough to interfere with speech is experienced by approximately 8 percent of U.S. adults and 1 percent of children. Hearing loss at this level has consequences for quality of life, development in children, and other problems. Occupational surveys list noise as the first or second most prevalent work hazard worldwide. More than 8 million U.S. workers are exposed to average eight hour noise levels exceeding 85 dBA, and of this number 500,000 are estimated by the Occupational Safety and Health Administration (OSHA) to be exposed to 100 dBA or greater. The principal health consequence of excessive noise exposure is permanent hearing loss, and the economic consequences of hearing loss are great. Workers compensation is estimated by the Alliance of American Insurers to average $80-$100 million each year, with the number of claims increasing each year.

The hearing examination will achieve the following objectives: 1) to obtain normative data on the hearing status of the adult US population; and 2) to evaluate certain covariates that may be related to hearing loss, such as occupational exposure.

Staff:

Medical technician

Protocol:

Methods: The hearing component for NHANES will test adolescents ages 12-19 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
- Physical examination of the outer ear

Eligibility:

- Participants age 12-19

Exclusion Criteria:

- 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: MEC physician evaluates all participants with the following findings and refers as appropriate:
- Otoscopy - impacted cerumen, drainage, blood in ear canal, foreign body in ear canal
- Tympanometry- Measures of pressure, compliance and volume consistent with blocked ear canal, fluid, or perforated eardrum
  - Level 3: Classification of hearing ability based on pure-tone audiometry

Text as is appears in MEC 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

> Provide interpretation of hearing test for right ear and left ear (**see Attachment 32**) .
> Provide recommendation if any threshold in either ear exceeds 25 dB HL as follows:

The audiometry test can identify a hearing problem but can not 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 – Bone Density Dual-energy X-ray Absorptiometry (DXA)

Public Health Objectives:
The body composition component consists of dual-energy X-ray absorptiometry (DXA) scans of the proximal femur (hip) and lumbar spine. The femur and spine scans will provide information on bone mineral content or density for sample persons ages 8 years and older.

Femur bone mineral density (BMD) data will address secular trends in femoral osteoporosis in the adult U.S. population since NHANES III, as called for by Objective 2.9 of Healthy People 2010. Data from the femur and spine scans will also enhance the evaluation of skeletal health in the U.S. population by providing: a) the first estimates of osteoporosis at the spine, an important site of osteoporotic fracture; b) the first national data on spine BMD for ages 8 years and older; and c) the first nationally representative data on femur BMD in individuals ages 8-19 years.

Low BMD is a major determinant of osteoporotic fracture risk. Hip fractures account for the majority of financial costs associated with osteoporotic fractures. It has been estimated that the cost of hip fractures is about $14 billion annually. Since the risk of hip fractures begins to increase exponentially after age 65, the magnitude of this problem is likely to increase dramatically over the next few decades as the population ages. Femur BMD is one of the variables included in the model to assess absolute fracture risk that is being developed by a committee of the National Osteoporosis Foundation (NOF) and International Osteoporosis Foundation (IOF).

NHANES is the only nationally representative survey that can shed light on when peak bone mass is attained and the degree of bone loss with age. Childhood and adolescence are the periods to target for intervention strategies in osteoporosis. Measurement in younger individuals will provide insight into early racial/ethnic differences in the rate of bone accretion. This information is vital to all aspects of treatment and prevention of this disease and is particularly critical to government funding of related research, medical screening, treatment, and reimbursement programs.

Measures of bone mineral content or density also will allow researchers to gain insights into age, sex, and racial/ethnic differences in the skeleton relative to other measures of body composition such as total muscle and fat mass, as well as behavioral factors such as diet and activity.

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:
Eight minutes are allowed for the procedure.

Health Measures:
Bone measures also will be obtained for pelvis, left and right ribs, thoracic and lumbar spine.
- 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 (%)

Femur scan: values are obtained for the neck, trochanter, intertrochanter, Ward's triangle, and total femur. Spine scan: values are obtained for the L1, L2, L3, and L4 vertebrae and total spine.

- Bone mineral content (gm)
- Bone area (cm^2)
- Bone mineral density (gm/cm^2)

Eligibility:
SPs who do not meet any of the safety/exclusion questions:

- Femur and lumbar spine scan: 8 years and older

Exclusion Criteria:
- Pregnancy
- History of radiographic contrast material (barium) use in past 72 hours
- Nuclear medicine studies in the past 3 days
- Weight over 300 pounds (limitation 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.
- Mentally impaired individuals will not be excluded from body composition because there is no contraindication.

Report of findings:

MEC None
NCHS
Level 1: None
Level 2: None
Level 3: Percentage body fat and bone density results

Bone mineral density (ages 20 and older) will be reported in the final report of findings sent to participants from NCHS. BMD results will not be reported to participants less than 20 of age because the reference group used for analyzing the BMD does not include persons less than 20 years.

Variables reported: Hip and spine bone mineral density (BMD) with interpretations using the T-score or Z-scores from analyzed scan. Males will be compared to a male reference dataset and females will be compared to a female reference dataset.

Body Measurements-Anthropometry

Public Health Objectives:
The objectives of the body measurements or 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) provide data to study the association between body measures and body composition; 3) study health conditions and health risk factors and conditions including cardiovascular disease, diabetes, hypertension, physical inactivity, and dietary patterns; and 4) to monitor growth and development in children. Overweight is a major public health problem in the United States. The recent increase in overweight prevalence among all sex, age, and racial-ethnic groups has 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 representative reference data, set health objectives, and monitor trends. Anthropometry data have been collected with comparable methods since the first National Health Examination Survey (1960-62).

Survey Staff: Trained health technicians perform all of the NHANES body measurements using standardized examination methods and calibrated equipment. A recorder assists the examiner during the body measures exam by assuring that proper positioning is maintained during the measurement process (particularly for young children), and recording information that is entered manually into the NHANES Integrated Survey Information System (ISIS), an online data entry system used for all of the NHANES examination components.

Measurement Site and Equipment: All measurements are performed in the NHANES mobile examination centers (MECs). The body measurement component is conducted in a private room that is equipped with a floor scale, fixed stadiometer, a bench (for taking measurements in a seated position), wall mirror, infant recumbent length measuring board, and computer workstation.

Target Sample Groups for the NHANES Body Measurement Assessments: All participants are eligible for this component. The measurements vary depending on the age of the participant as follows:

Weight: all ages Recumbent length: birth through 47 months
Standing height: 2+ years Upper leg length: 8+ years
Upper arm length: 2+ months Head circumference: birth through age 6 months
Mid-upper arm circumference: 2+ months Waist circumference: 2+ years
Triceps skinfold: 2+ months
Subscapular skinfold: 2+ months

Protocol Description

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" (set to zero) with the parent on the scale; the child is handed to the parent and the child's weight is measured. All body weight data are captured electronically and entered into the survey database automatically.

Stature (Standing Height): Height is measured using a wall-mounted stadiometer. The device is connected to an automated data electronic database and data are entered into the survey database automatically.

Recumbent Length: Length is measured using an infantometer or measuring board. The device is connected to an automated data electronic database and data are entered into the survey 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.

Skinfold Thickness Measurements: Sub-scapular and triceps skinfold measurements are made using skinfold

calipers.

Time Allotment: Approximately 4-5 minutes, depending on the age of the subject.

Cardiovascular Fitness

Public Health Objectives:

Low levels of physical activity and physical fitness are surely the most important public health problem on which we have such limited data. Reports on population attributable risk place inactivity in the same general category as tobacco use and unhealthful diet as problems, yet the amount of data from nationally representative samples on smoking and diet is several orders of magnitude greater that the data on physical activity, and there are no data on physical fitness on a nationally representative population of U.S. adults.

Evaluation of cardiovascular fitness will: 1) provide nationally representative data on cardiovascular fitness; 2) estimate the prevalence of persons at risk due to poor physical fitness; and 3) provide data to study the association between cardiovascular fitness and other health conditions and risk factors, such as obesity, cardiovascular disease, diabetes, hypertension, and activity and dietary patterns.

Staff:
Health technician (MEC) and physician

Protocol:

Methods:

The protocol is a submaximal exercise test. The exam consists of a 2 minute warm up, two 3 minute exercise periods, and a 3 minute recovery period. The grade and speed of the treadmill during exercise are determined by: 1) the participant's physical activity readiness determined by responses to the household interview, 2) age, and 3) BMI. During the first stage of the exercise period, the participant should attain approximately 55-65% of age-predicted maximal heart rate (APMHR). During the second stage, the participant should attain approximately 70-80% APMHR. Time Allotment: 22 minutes Health Measures: Pre-test heart rate and blood pressures will be captured and stored by ISIS. Additionally, at the end of warm-up, each exercise stage, and each minute of recovery, the ISIS will capture:

- Heart rate (bpm)
- Systolic blood pressure (mm Hg)
- Diastolic blood pressure (mm Hg)
- Treadmill speed and grade (mph, %)

From the exercise heart rate and treadmill settings, maximal work capacity will be predicted. Predictedmaximal work capacity is the measure of fitness obtained.

Eligibility:
Sample persons aged 12-49 years in the afternoon session who do not meet any of the exclusion criteria

Exclusion Criteria:

All persons not excluded by household questionnaire will be evaluated by the MEC physician for eligibility for the CV fitness component. Physician will follow the protocol for medical exclusion based on responses to safety exclusion questions, pulse and blood pressure.

Exclusions based on household interview and/or other components:

- Any amputations of legs and feet other than toes
- Self reported weight > 350 pounds, exclude
- Pacemaker or automatic defibrillator
- Pregnancy greater than 12 weeks

Exclusions based on household interview Medical Conditions and Health Status (COQ) (if 1, 7, or 9 exclude)

- COQ.160b Congestive heart failure
- COQ.160c Coronary heart disease
- COQ.160d Angina pectoris
- COQ.160e Myocardial infarction
- COQ.160f Stroke
- COQ.160 Emphysema

Physical Functioning - (PFQ) - (if 3, 4, 7, or 9, exclude)

- PFQ.060b Difficulty walking for a quarter mile (2-3 blocks)
- PFQ.060c Difficulty walking up 10 steps without resting
- PFQ.060h Walking from one room to another on the same level

- PFQ060I Standing up from an armless straight chair
  (if 1,7, or 9, exclude)

- PFQ.090 Use of a device such as a cane or wheelchair
  (if 2,5,6,7,8,10,12,16, 97, 99 exclude)

- PFQ.067 2=Back or Neck Problem
  5=Depression/Anxiety/Emotional Problem
  6=Developmental Problems (Cerebral Palsy)
  7=Diabetes
  10=Heart Problem
  12=Lung/Breathing Problem
  16=Stroke Problem

Diabetes (DIQ) (if 1,7, or 9, exclude)

- DIQ.080 Retinopathy

Cardiovascular (CAQ)- (if 1, 7, or 9)

- CAQ.030 Stop when walking at own pace on the level
- CAQ.040 SOB after walking 100 yards or few minutes on the level
- CAQ.050 PND
- CAQ.060 PND relieved by sitting on side of bed
- CAQ.070 Orthopnea

Respiratory Health (RSQ) - (if 55 {code for 12 or more attacks], 77, or 99 exclude)

- RSQ.080 Wheezing in past 12 months (if 1,7,or 9, exclude)
- RSQ.110 Wheezing that limits speech (last 12 months)

Vision (VSQ) -

- VSQ.020 Blind (if 1,7, or 9, exclude)
- VSQ.030 Very poor eyesight (if 1,7, or 9, exclude)
- DSQ.240 medications will be available in SP History in Physician's Exam. Physician will check this list and exclude based on medication on the Exclusion list below. (See questions 9- 14 below)

Cardiovascular Safety and Exclusion Questions (Asked in Physician's Exam):
(If Yes or Don't Know, exclude unless otherwise indicated)

1. Have you been hospitalized in the past 3 months? (See exclusion list below)

2. (12-19 years only) Has a doctor ever said you should not participate in sports or other activities because of a health condition?

3. Has a doctor ever said you have a heart condition and that you should only do physical activity recommended by a doctor?

4. (20-49 years only) Do you feel pain in your chest when you do physical activity?

5. (20-49 years only) In the past month, have you had chest pain when you were not doing physical activity? (Probe: Have you seen a medical doctor about your chest pain? Did the doctor tell you that the chest pain was related to your heart?)

6. Do you lose your balance because of dizziness? (Probe: Is this an isolated incident or does it occur on a regular basis?)

7. Do you ever lose consciousness? (Probes: Did this occur as a result of illness or was it unexplained? Is this an isolated incident or does it occur on a regular basis?

8. Do you have a bone or joint problem that could be made worse by walking? (Probe: Do you think you can do the test without injuring yourself?

9. Are you currently taking any prescription medications? (yes go to 10, no go to 15)

10. Are you currently taking any prescription medications for your blood pressure? (yes go to 11, no go to 14)

11. What is the name of this medication? _____. (If medication is on list, exclude. If not on list, go to 12.

12. Are you taking any other medication for your blood pressure? (Yes, go to 13/ No go to 14./Don't Know, exclude.)

13. What is the name of this medication? _____. (If medication is on list, exclude. If not on list, go to 14.)

14. Are you currently taking prescription medications for the following conditions:
    · heart condition Yes/No/Don't Know (If Yes or Don't Know, exclude)
    · prescription eye drops for glaucoma (If Yes or Don't Know, exclude)

15. Do you know of any other reason why you should not do a treadmill test?

Question 1: List of reasons for exclusion based on hospitalization from ACSM Guidelines, 5th edition, page 42.

- A recent significant change in the resting ECG suggesting infarction or other acute cardiac event.
- Recent complicated myocardial infarction
- Unstable angina
- Uncontrolled ventricular arrhythmia
- Uncontrolled atrial arrhythmia that comprimises cardiac function
- Third degree AV heart block
- Acute congestive heart failure · Severe aortic stenosis
- Suspected or known dissecting aneurysm
- Active or suspected myocarditis or pericarditis
- Thrombophlebitis or intracardiac thrombi
- Recent systemic or pulmonary embolus
- Acute infections
- Significant emotional distress (psychosis)
- Moderate valvular heart disease
- Known electrolye abnormalities
- Fixed rate pacemaker
- Frequent or complex ventricular ectopy
- Ventricular aneurysm
- Uncontrolled metabolic disease (diabetes, thyrotoxicosis, myxedema, etc)
- Chronic infections disease (mononucleosis, hepatitis, AIDS)
- Neuromuscular, musculoskeletal, or rheumatoid disorders that are
- exacerbated by exercise · Complicated pregnancy (N.B. this is an exception to the ASCM guidelines - the guidelines also include advanced pregnancy)

Questions 9-14: Exclusion Medication List

Antianginal Agents

Calcium Channel-Blockers
Bepridil (Vascor)
Diltiazem (Cardizem)
Verapamil (Calan, Isoptin)

Anti Arrhythmics

Amiodarone (Cordarone)
Bretylium (Bretylol)
Disopyramide (Norpace)
Encainide (Enkaid)
Ethmozine (Moricizine)
Flecanide (Tambocor)
Lidocaine (Xylocaine, Xylocard)
Mexiletine (Mexitil)
Procainamide (Pronestyl, Procan SR)
Propafenone
Sotalol (Betapace)
Tocainide (Tonocard)
Quinidine (Quinidex, Quinaglute)

Beta Blockers

Acebutolol (Sectral)
Atenolol (Tenormin)
Betaxolol (Kerlone)
Bisoprolol (Zebeta)
Cartelol (Cartrol)
Labetalol (Normodyne)
Metoprolol tartrate (Lopressor)
Nadolol (Corgard)
Pindolol (Visken)
Propranolol (Inderal)
Timolol (Blocardren)

Eye Drops

Betoptic Eyedrops Timoptic Eyedrops
Nitrates and Nitroglycerin
Isosorbide dinitrate (Isordil, Diltrate)
Nitroglycerin (Nitrostat, Nitrolingual spray)
Nitroglycerin ointment (Nitrol ointment)
Nitroglycerin patches (Transderm Nitro, Nitro-Dur II, Nitrodisc)
Isosorbide mononitrate (Ismo, Monoket)
Pentaerythritol tetranitrate (Cardilate)

Digitalis

Digoxin (Lanoxin)

Physician exam exclusions:
If participants resting pulse rate is > 100 bpm or systolic blood pressure > 180 mm Hg.

Criteria for stopping during the fitness protocol:
- Onset of angina or angina-like symptoms
- Significant drop (20mmHg) in SBP or a failure of the SBP to rise with an increase in exercise intensity
- Excessive rise in BP: SBP >260 mmHg or DBP >115 mmHg
- Signs of poor perfusion: lightheadedness, confusion, ataxia, pallor, cyanosis, nausea, or cold and clammy skin
- Failure of heart rate to increase with increased exercise intensity
- Subject requests to stop
- Physical or verbal manifestations of severe fatigue
- Unusual or severe shortness of breath
- Leg pains or cramps
- Failure of the testing equipment
- Severe headache
- Visual disturbances
- %HRmax >90% and SP appears/feels exhausted
- Unable to complete test without holding on to the handrail

Justification for using vulnerable populations:
- Minors are included in the cardiovascular fitness assessment to obtain information on fitness among adolescents.
- Pregnant women will be excluded from fitness testing because physiologic changes with pregnancy affect heart rate, and therefore the interpretation of the data. The exclusion also considers safety.
- Mentally impaired individuals will be excluded from the treadmill test.

Risks:

- There is much experience across the country to suggest that submaximal testing in a healthy population poses minimal health risk. Persons with any conditions that may increase risk of adverse outcome on the treadmill will be excluded. Risk associated with this test in a screened population include fatigue, muscle soreness, exercise-induced asthma, and chest tightness.

- The Cooper Institute for Aerobic Research and Stanford University have conducted tens of thousands of submaximal tests similar to what is proposed in NHANES. These tests were conducted in community survey centers and work-site health promotion programs. They were done after screening and determination of eligibility by a nurse or exercise technician with no physician supervision, other than supervising training and monitoring for quality control. There have been no complications from these tests. No one even missed 30 minutes of work due to delay caused by some incident related to the exercise test. This accumulated experience also points to the low risk associated with submaximal exercise testing in an apparently

healthy population. There is also no problem associated with conducting the exercise test after venipuncture. That is the procedure followed in most exercise laboratories including the Cooper Clinic and Stanford surveys since exercise changes hemoconcentration and provides inaccurate readings for lipids etc.

Report of findings:

MEC:

Level 1: MEC Physician notified if participant has acute chest pain, acute respiratory distress or signs of hemodynamic instability. If the participant is deemed medically unstable, emergency medical procedures will be instituted.

Level 2: If the MEC Physician determines that a condition discovered during fitness testing requires follow-up by a community physician, a referral will be made.

Level 3: Grade, speed, test duration, and general fitness classification relative to same sex and age group based on estimated maximum work capacity (V02 max).

Text in MEC report is as follows:

Your fitness test was done on a treadmill. The test consisted of a warm-up, two exercise periods (stage 1 and stage 2), and a recovery period. The table below shows your test results.

Stage	Required Time	Your Time	Your Heart Rate
Warmup	2 min		
Stage 1	3 min		
Stage 2	3 min		
Recovery	2 – 3 min(s)		

During this exercise your maximum incline on the treadmill was ___%, and your maximum speed was___mph. Compared with other people of your age and sex, your cardiovascular fitness level is _____ . (Superior, excellent, good, fair, poor, very poor).

Food Propensity Questionnaire (FPQ)

Public Health Objectives:

The FPQ will be used improve estimates of usual food intake, particularly infrequently consumed foods such as leafy green vegetables and whole grain products. The NHANES FPQ and 24-hour dietary recall data provide an individual-level link between usual dietary intake and the NHANES health data. FPQ data will be used to estimate the number and percent of persons in the U.S. population and targeted subgroups with selected risk factors; monitor trends in diet behavior and environmental exposures; establish, and produce a national probability sample of baseline information on health and nutritional status.

Mode of Data Collection: A 23-page paper form is mailed to respondents; forms are returned in a postage-paid envelope. The FPQ items ascertain frequency of consumption information; closed-ended response choices are listed for the food or food group items in the instrument. No portion size information is obtained. There are no plans to estimate nutrient intakes using the FPQ data. The propensity data will be used in statistical models to estimate usual food intake.

Protocol

Methods: FPQ forms are mailed to examinees' homes after the second 24-hour dietary recall interview (telephone mode) is completed. The completed FPQ forms are returned by mail to Westat, Inc. for processing using an optical scanning method. Respondents receive remuneration of $30 for returning the FPQ form.

Time Allotment: The estimated time to complete the FPQ is 30 minutes.

Target Sample: Examined persons 2+ years of age with dietary interview data

Eligibility: Examined persons 2+ years of age who are able to complete an English or Spanish language FPQ form.

Exclusion Criteria: None

Justification for using vulnerable populations:
Minors are included in this component because they are an important target population group. A proxy completes the form for children 2-5 years of age proxies assist 6-11 year old children. Persons 12 years of age and older self- report.
There is no reason to exclude mentally impaired or handicapped individuals. A proxy respondent who is knowledgeable about the survey participant's diet can complete the form.

Risks: None

Report of Findings: No reporting is involved with this component.

Ophthalmology

Public Health Objective: The leading causes of visual impairment in the United States are primarily age-related eye diseases including cataract, diabetic retinopathy, glaucoma, and age-related macular degeneration. More than 3.4 million Americans aged 40 years or older are either blind or are visually impaired. The major causes of vision loss in older Americans are age-related macular degeneration (AMD), diabetic retinopathy, cataract and glaucoma. Visual impairment is one of the 10 most common causes of disability in America and is estimated to impose an economic burden of $38.4 billion ($22.3 in direct costs and $16.1 in indirect costs).

Age-related macular degeneration (AMD) is the leading cause of visual impairment and blindness in the U.S. among people 65 years or older. The frequency of AMD is expected to increase as the population lives longer. Population based estimates of the prevalence and severity of AMD will help allocate resources as treatment modalities become available.

Diabetic retinopathy is the leading cause of new blindness among adults age 20-74 years. It can affect almost anyone with diabetes and contribute both to individual and societal burden. With the growing epidemic of diabetes and demographic changes in the American society, vision loss and eye disease will be a growing major public health problem. Efficacious and cost-effective strategies to detect and timely treat diabetic retinopathy are available, but among people with diabetes, ocular eye examination is received only by two-thirds of people for whom the exam is recommended and varies significantly across health care settings.

Glaucoma is the leading cause of irreversible blindness and a prevalent disease associated with aging. Although glaucoma can usually be controlled by early detection and treatment, half of people with glaucoma are not diagnosed, and glaucoma is still the number one blinding disease among African Americans.

Staff:

Health technician

Protocol: Prior to the ophthalmology exam, the participant will complete the vision examination component which includes visual acuity and objective refraction. The first exam performed will be the visual field testing using Frequency Doubling Technology (FDT) to test visual field loss from glaucoma. The second exam will be performed using an ophthalmic digital imaging system (Retinal Photography) to assess the presence of retinal diseases. Data are sent to image graders on DVD for grading following a strict protocol.

Time Allotment: The average time needed to complete both exams is 18-20 minutes

Health Measures:

- Presence of diabetic retinopathy
- Presence of age-related macular degeneration
- Evaluation of visual loss from glaucoma

Eligibility:

All examined participants aged 40 years and older who do not meet any of the exclusion criteria

Exclusion criteria:

Participants with:

- Lack of light perception (as measured by question VIQ010 in the household interview)
- Severe eye infection in one or both eyes (Question VIQ110)
- Individuals wearing eye patches in both eyes (Question VIQ130)

Justification for using vulnerable populations:
Current estimates of eye disease are based on data that are 25 years old and not nationally representative. Inclusion of mentally impaired individuals and pregnant women are important for national estimates.

Risks:
The examination procedures are noninvasive and present no greater than minimal risk to subjects.

Report of findings:
Findings from the NHANES Ophthalmology component will be provided in the Final Report of Findings sent to participants 12-16 weeks after the examination. Abnormal results will be reported to participants as soon as possible, in the Early Report.

Early Report of pathology:

The Medical Officer will send a letter to the participant within 24 hours of receiving the results. Pathologies will be reported by the name of the eye condition and a brief description (refer below). A statement recommending an appointment with an eye doctor (ophthalmologist) within the next TWO MONTHS or AS SOON AS POSSIBLE will also be provided based on the condition severity.

Description of the eye pathology provided in the early report:

- Active Proliferative Retinopathy "There were changes in the retina, the back of your eye, that are often found in people with diabetes. These changes were found in (the right/the left/both) eye(s)."
- Severe Non-Proliferative Retinopathy "There were changes in the retina, the back of your eye, that are often found in people with diabetes. These changes were found in (your right/your left/both) eye(s)."
- Macular Edema "There is a swelling in the retina in the back of (your right/your left/both) eye(s), called macular edema. This swelling can cause a decrease in vision."
- Treatable Late Stage Age-Related Macular Degeneration "Signs of age-related macular degeneration were found in (your right/your left/both) eye(s). Age-related macular degeneration is a common eye disease in older people."
- Branch or Central Vein Occlusion "There appears to be a blockage or an occlusion of a small retinal blood vessel in the back of (your right/your left/both) eye(s)."
- Hollenhorst Plaque "We found a piece of cholesterol (fatty deposit) lodged in the small retinal blood vessels in the back of (your right/your left/both) eye(s) suggesting the possibility of changes in the carotid artery in your neck."
- Irregular Nevus "A choroidal nevus, a small mole, like a birthmark, was found in the back of (your right/your left/ both) eye (s). This nevus had an unusual appearance."
- Macular Hole "There is a small hole in the central part of the retina (the macula) in (the right/the left/both) eye(s). A macular hole can cause a decrease in vision. The cause of macular holes is unknown."
- Surface Wrinkling Retinopathy/Epiretinal Membrane "There is a clear layer or membrane present in the center of the retina in (your right/your left/both) eye(s) that is pulling on the retina and may be causing a decrease in vision."
- Suspicious Cup to Disc Ratio "The optic nerve (the main nerve going into the eye) in (your right/your left/both) eye(s) has changes that suggest glaucoma may be present."

Final Report of Findings:
The findings reported will be reported in two categories:

1. Visual Field Test Results

Visual field test results will be reported for each eye. The definition of a visual field abnormality (eye-specific) is any two fields on an FDT below 1% threshold level in first test, AND at least two fields below 1% threshold level in second test, AND at least one of which is the SAME field as in the first test. "We did a visual field test to find out

how well you can see things peripherally or out to the side.

Your visual field test was <normal> or <outside normal limits> in your right eye, and <normal> or <outside normal limits> in your left eye. If either eye abnormal, add: This may suggest an eye problem, which should be evaluated by an eye doctor within the next two months."

2. Retinal Image Findings

In certain cases, the participant may have received a pathology notification earlier. Reported findings may be the same as the previous pathology notification or may contain additional information about other less severe conditions.

No Significant Abnormalities "No significant abnormalities were found in the back of your (right/left) eye(s)."

Ungradeable Images "Unfortunately, we were unable to evaluate the photographs of the back (the retina) of (your right/your left/either) eye."

Abnormalities Present When a condition is present, the following feedback text is provided:

Age-related macular degeneration

- Drusen only without other signs of age-related macular degeneration

  "Drusen, small deposits in the retina (the back layer of your eye) were found in (your right/your left/both) eye(s). These are commonly seen as people get older."

- Early age-related macular degeneration

  "Early signs of age-related macular degeneration were found in (your right/your left/ both) eye(s). Age-related macular degeneration is a common disease sometimes associated with decreased vision."

- Late age-related macular degeneration

  "Signs of age-related macular degeneration were found in (your right/your left/both) eye(s). Age-related macular degeneration is a common eye disease in older people."

- Treatable Late Age-Related Macular Degeneration

  "Signs of age-related macular degeneration were found in (your right/your left/both) eye(s). Age-related macular degeneration is a common eye disease in older people." If you have not already done so, it is strongly recommended that you make an appointment with an eye doctor (ophthalmologist) as soon as possible.

Diabetic Retinopathy

- Non-Proliferative Retinopathy

  "There were changes in the retina, the back of your eye, that are often found in people with diabetes and occasionally in people with high blood pressure. These changes were found in (the right/the left/both) eye(s). It is recommended that you make an appointment with an eye doctor (ophthalmologist)."

- Severe Non-Proliferative Retinopathy:

  "There were changes in the retina, the back of your eye, that are often found in people with diabetes. These changes were found in (the right/the left/both) eye(s). If you have not already done so, it is strongly recommended that you make an appointment with an eye doctor (ophthalmologist)."

- Inactive Proliferative Retinopathy:

  "There were changes in the retina, the back of your eye, that are often found in people with diabetes. These changes appeared to be old and inactive and were found in (the right/the left/both) eye(s). "

- Active Proliferative Retinopathy:

  "There were changes in the retina, the back of your eye, that are often found in people with diabetes. These changes were found in (the right/the left/both) eye(s). If you have not already done so, it is strongly recommended that you make an appointment with an eye doctor (ophthalmologist) as soon as possible."

Macular Edema

- Macular edema, not clinically significant (no pathology notification sent):

  "There is a swelling in the retina in the back of (the right/the left/both) eye(s), called macular edema. This swelling can cause a decrease in vision. It is recommended that you make an appointment with an eye doctor (ophthalmologist)."

- Macular edema, not clinically significant (pathology notification sent):

  "There is a swelling in the retina in the back of (the right/the left/both) eye(s), called macular edema. This swelling can cause a decrease in vision. If you have not already done so, it is recommended that you make an appointment with an eye doctor (ophthalmologist) as soon as possible."

- Clinically significant macular edema:

  "There is a swelling in the retina in the back of (the right/the left/both) eye(s), called macular edema. This swelling can cause a decrease in vision. If you have not already done so, it is strongly recommended that you make an appointment with an eye doctor (ophthalmologist) as soon as possible."

Branch/Central Vein Occlusion

- Branch/Central Vein Occlusion present (no pathology notification sent)

  "There appears to be a blockage or an occlusion of a small retinal blood vessel in the back of (your right/your left/both) eye(s). This blockage may have happened a while ago. No further evaluation is required."

- Branch/Central Vein Occlusion present (early pathology notification sent)

  "There appears to be a blockage or an occlusion of a small retinal blood vessel in the back of (your right/your left/both) eye(s). If you have not already done so, it is recommended that you make an appointment with an eye doctor (ophthalmologist)."

- Branch/Central Vein Occlusion present (immediate pathology notification sent)

  "There appears to be a blockage or an occlusion of a small retinal blood vessel in the back of (your right/your left/both) eye(s). If you have not already done so, it is strongly recommended that you make an appointment with an eye doctor (ophthalmologist) as soon as possible."

Hollenhorst Plaque

- Hollenhorst plaque present

"We found a piece of cholesterol (fatty deposit) lodged in the small retinal blood vessels in the back of (your right/your left/both) eye(s) suggesting the possibility of changes in the carotid artery in your neck. If you have not already done so, it is recommended that you make an appointment with an eye doctor (ophthalmologist) as soon as possible."

Nevus

- Nevus present (no pathology notification sent)

  "A choroidal nevus, a small mole, like a birthmark, was found in the back of (your right/your left/ both) eye (s). This should be watched periodically by your eye doctor (ophthalmologist). "

- Nevus present (no pathology notification sent)

  "A choroidal nevus, a small mole, like a birthmark, was found in the back of (your right/your left/ both) eye (s). This nevus had an unusual appearance. If you have not already done so, you should make an appointment with an eye doctor (ophthalmologist) as soon as possible."

Macular Hole

- Macular hole present (no pathology notification sent)

  "There is a small hole in the central part of the retina (the macula) in (the right/the left/both) eye(s). A macular hole can cause a decrease in vision. The cause of macular holes is unknown. It is recommended that you make an appointment with an eye doctor (ophthalmologist)."

- Macular hole present (pathology notification sent)

  "There is a small hole in the central part of the retina (the macula) in (the right/the left/both) eye(s). A macular hole can cause a decrease in vision. The cause of macular holes is unknown. If you have not already done so, it is recommended that you make an appointment with an eye doctor (ophthalmologist)."

Large Cup to Disc Ratio

- Large cup to disc ratio $\geq$ 0.7 (pathology notification sent)

  "The optic nerve (the main nerve going into the eye) in (the right/the left/both) eye(s) has changes that suggest glaucoma may be present. If you are not currently being followed by an eye doctor (ophthalmologist), it is recommended that you make an appointment."

Surface Wrinkling Retinopathy/Epiretinal Membrane

- Surface wrinkling retinopathy-traction is present (no pathology notification sent)

  "There is a clear layer or membrane present in the center of the retina in (the right/the left/both) eye(s) that may be pulling on the retina and may be causing a decrease in vision. If you have noticed a change in your vision, it is recommended that you make an appointment with an eye doctor (ophthalmologist)."

- Surface wrinkling retinopathy-traction is present (pathology notification sent)

  "There is a clear layer or membrane present in the center of the retina in (the right/the left/both) eye(s) that is be pulling on the retina and may be causing a decrease in vision. If you have not already done so, it is strongly recommended that you make an appointment with an eye doctor (ophthalmologist) as soon as possible."

Oral Glucose Tolerance Test (OGTT)

Public Health Objectives: Diabetes mellitus will be assessed by fasting measures of plasma glucose and an oral glucose tolerance test in examinees ages 12 years and over.

Diabetes is a large, growing, and costly public health problem in the United States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and over 1 million new cases of diabetes are diagnosed each year. Diabetes is the leading cause of kidney failure, non-traumatic lower extremity amputation, and blindness in working-age adults, and an estimated $135 billion were spent on direct and indirect medical costs for diabetes in 2002. Alarmingly, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults less than 40 years of age.

The inclusion of OGTTs on NHANES will allow estimation of the prevalence of IGT and, thus, pre-diabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and pre-diabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and pre-diabetes are particularly important as the nation initiates efforts to prevent diabetes among persons with pre-diabetes. These data on IGT and pre-diabetes are critical to targeting, designing, and evaluating prevention efforts, such as DHHS's STEPS program and efforts by the National Diabetes Education Program.

Staff:

. Phlebotomist
. Medical Technologist
. MEC Interviewer – administers Trutol

Protocol:

. **Method:**

A fasting glucose blood test is performed on all participants 12 years and older who are examined in the morning session after a 9-hour fast. After the venipuncture, participants are asked to drink 75 milligrams of Trutol® and to have a second venipuncture 2 hours (plus or minus 15 minutes) after the first venipuncture.

. **Time Allotment:**

Depending on age, 5-10 minutes.

. **Health Measures**

- o Determine a national estimate of diabetes disease prevalence (diagnosed and undiagnosed)
- o Identify the risk factors of diabetes disease;

. **Eligibility:**

o Only sample participants aged 12 years or more are eligible

. **Exclusion Criteria for Blood Draw:**

- o hemophilia
- o receiving cancer chemotherapy

. **Additional Exclusions for the OGTT:**

o taking oral medications for diabetes
o on insulin
o pregnant
o or if they have not fasted 9 hours

. **Risks/Benefits:**

- There are minimal risks associated with this procedure. The package label for Trutol® lists the following rare but known adverse reactions: nausea, vomiting, abdominal bloating and headache. In addition, there is a rare incidence of hypoglycemia. The risks associated with venipuncture include excessive bleeding, fainting/feeling lightheaded, hematoma, infection, and multiple punctures to identify veins. Participants eligible for OGTT will have to endure

- Management of adverse reactions
  Board certified physicians are members of the NHANES exam team. If an adverse reaction occurs, a staff member will ask the physician to evaluate the participant and provide basic medical support. The physicians are prepared to refer participants to their own physician, community clinics, or the emergency room. MEC staff is certified in American Heart Association Basic Life Support. Emergency procedure drills are conducted twice a year.

Report of Findings

- Findings form the NHANES OGTT component will be provided in the Final Report of Findings sent to participants 12-16 weeks after the examination. Abnormal results will be reported to participants as soon as possible. For any early reporting of fasting glucose and two-hour glucose results the Medical Officer will send a letter to the participant within 24 hours of receiving the results. Participants in the morning examination session get plasma glucose reported if the fasting level is $\geq$ 126(if fasting 9 hrs) or $\geq$ 200(if fasting <9 hrs).

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 Basic Screening Exam (BSE) will collect information on untreated caries, dental restorations, and dental sealants during the data collection cycle.

Oral health data from NHANES will be used for:

. Assessing the prevalence of major oral health diseases and conditions including dental caries and edentulism.
. Assessing dental caries prevention efforts
. Evaluating specific public health programs/new policies and initiatives
. Targeting minority/underserved populations for monitoring of health status
. Evaluating 5 Healthy People 2010 objectives related to oral health

Staff:

Health Technician/Technologist (HT)

Protocol: The oral health screening consists largely of visual examination with a limited questionnaire. The assessments are conducted using a disposable dental mirror.

. **Time Allotment:**

Depending on age, 2-4 minutes.

. **Health Measures and Eligibility:**

Only sample participants aged 5 years or more are eligible for one or more parts of the exam. The following oral health subcomponents for the examination component and the age groups of interest in parentheses are:

- o Denture Questionnaire (25 years and older);
- o Tooth Count (5 years and older);
- o Oral Health BSE (5 years and older);
- o Functional Occlusal Contacts Exam (25 years and older); and
- o Report of Findings (5 years and older)

Exclusion Criteria:

None.

. **Justification for using vulnerable populations:**

- o 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.
- o 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), hazardous material (no use of 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 given to the participant at the conclusion of the examination 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.

MEC levels of referral:

. If there are no findings, the following text will be printed:

o Level 1: Referral Code "N" "…after inspecting your (your child's) teeth, we did not find anything requiring immediate attention. However, our inspection is not a diagnosis and you should continue visiting your dentist on a regular basis, as recommended."

. If there is at least one untreated decay lesion, the following text will be printed:

o Level 2: Referral Code "Y" "…after inspecting your (your child's) teeth, we found that you (your child) may need dental care. However, our inspection is not a diagnosis. Therefore, you should make an appointment with your dentist within the next 1-2 weeks to have a detailed examination, diagnosis, and treatment."

Physical Activity Monitor (PAM) Component

Public Health Objectives: The primary objective of the component is to assess intensity and duration of physical activity levels of U.S. children and adults. *The U.S. Surgeon General's Report on Physical Activity and Health* reported that more than 60 percent of Americans do not engage in regular physical activity and that 25 percent do not engage in any activity. The report reaffirmed the importance of regular moderate or vigorous-intensity activity. Until now, it has been difficult to assess actual physical activity levels in freeliving populations because the cost and complexity of performing the monitoring tasks required to obtain this information were prohibitive. Physical activity data on children, particularly children in the 6-11 year age group are lacking. Proxy information on physical activity levels among youth are not useful because children spend large amounts of time away from home and they also engage in sporadic periods of activity that are difficult to document, let alone quantify. Activity monitors provide a reliable, objective, and accurate method to assess the intensity and duration of physical activity levels in children and adults.

Staff: A trained health or medical technician initializes the activity monitors in the mobile examination center (MEC).

Protocol: Examined persons are asked to wear the monitor for 7 days during normal waking hours. The monitors are not waterproof and must be removed prior to swimming or bathing. The monitor is worn on a flexible waist belt and can be removed easily. After 7 days of wear, participants return the monitor by mail in a postage-paid envelope. Respondents receive $40 remuneration for returning their monitors.

Eligibility: Ambulatory subjects 6 years of age and over are asked to wear activity monitors.

Time Requirement: It takes approximately three (3) minutes to explain the component, initialize the monitor to record information, and fit the monitor belt on each subject.

Device: The ActiGraph (formerly MTI/CSA) Model 7164 accelerometer manufactured by ActiGraph, Ft. Walton Beach, FL is used. Devices are calibrated prior to use in the study. The device is worn on an elastic waist belt over the right hip (underneath clothing).

Report of findings: There is no report of findings for this component.

Physician's 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:

Methods:

- 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.
- Cardiovascular exclusion screening questions will be asked by physician (see Cardiovascular Fitness)
- 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 which will be used at the time of reporting results. Physician will answer any questions the participants may have about the STD or HIV testing. Attachment 34 is a brochure with information about STDs to be used by the physician.

Time Allotment:

Depends on age of sample person. Range 2-13 minutes.

Health Measures:

Blood pressure

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

Eligibility:

Sample persons who do not meet the exclusion criteria

- Pulse: 2 months and older
- Blood pressure: 8 years and older
- Cardiovascular fitness screening: 12-49 years
- STD/HIV counseling: 14-49 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.
- Blood pressure cuff too small to fit on arm

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 not be excluded from the physician's exam because there is no contraindication; however the person's guardian will receive the report of findings and facilitate any referral if necessary.

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: 140 < Systolic BP < 210 and/or 90 <=diastolic BP < 120
Level 3: Systolic < 140 and diastolic < 90.

Text in MEC report is as follows:
Resting pulse rate (all ages)

Value	**Optimal**	**Normal**	**Acceptable**
Systolic	< 120	< 130	<140
Diastolic	< 80	< 85	< 90

Your blood pressure today is *insert statement from table below*

Systolic	*Diastolic*	*Statement*
< 130	< 85	within the normal range
130-139	85-90	normal but at the high end of the normal range
140-159	90-99	mildly high
160-179	100-109	moderately high
180-209	110-119	very high
>210	>120	severely high

From the Sixth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure

Children's BP levels reported as normal, high normal, high, and very high based on criteria established by the following manuscript: National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report from the National High Blood Pressure Education Program. Pediatrics. 1996;11:649-658.

- NCHS STD/HIV - Toll free phone line for participant to call for results
  Level 1: None
  Level 2: Positive results for chlamydia, gonorrhea, Herpes type 2 or HIV. Participants will be counseled by health educator and referred for care. List of STD/HIV treatment sites will be obtained in advance for each stand and be made available for participants
  Level 3: Negative results for chlamydia, gonorrhea, Herpes type 2 and HIV.

Respiratory Health

Public Health Objectives:

The Respiratory Health component includes two examinations: Spirometry (lung function testing) and Exhaled Nitric Oxide testing. The objective of the spirometry data collection is to assess the prevalence of asthma and adult chronic obstructive pulmonary disease (COPD) in the U.S. population. The data will also be used to produce updated reference data for the general population. Comparisons of resulting data with that of previous studies will illuminate trends in asthma and COPD prevalence over time in the United States. Exhaled nitric oxide (ENO) provides a measure of airway inflammation, a factor in the causal pathway of asthma and possibly other lung diseases. Currently there are no U.S. estimates for healthy persons or for those persons with asthma or COPD. The primary goals of the ENO testing are to 1) provide population estimates for ENO; 2) to examine the association between a marker for airway inflammation with other measures of lung function as well as with other biologic indices; and 3) to define the prevalence of undiagnosed airway inflammation;

Staff:

Health technician (MEC) and Physician

Protocol:

Methods:

Spirometry: The Spirometric testing protocol for baseline spirometry will be the same as in NHANES III and meet current American Thoracic Society (ATS) Guidelines for Spirometric Testing. The participants complete and a minimum of three but no more than eight full single breath tests according to ATS guidelines. These 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. Test will be performed routinely in a standing position, but if necessary participants will be allowed to sit during testing.

The spirometry component will include a subcomponent in which the spirometry exam will be repeated on a small subset of participants following the administration of a bronchodilator medication by the MEC physician. This will make it possible to distinguish between COPD and asthma, which have similar baseline spirometry profiles but differ in post-bronchodilator spirometry testing. This distinction is important because, although asthma and COPD have similar symptoms, they are associated with different risk factors and molecular and patho-physiologic mechanisms.

ENO: The NIOX MINO^{TM} monitor will be used to measure fractional exhaled nitric oxide in the exhaled breath of NHANES participants. This device follows the American Thoracic Society and European Respiratory Society 2005 equipment recommendations for the measurement of exhaled nitric oxide. The test requires two acceptable maneuvers (10 seconds for adults, and 6 seconds for youths) which will be averaged.

Health measures:

Spirometry: Forced Vital Capacity (FVC), Forced Expiratory Volume in one second (FEV1), and their ratio (the FEV1/FVC %), Peakflow (L/sec) FEF25-75% (L/sec)

ENO: exhaled nitric oxide (ppb)

Eligibility:

Sample persons aged 6 – 79 years who do not meet any of the exclusion criteria.

Exclusion criteria

Full Respiratory Health Component:

Affirmative responses to:

- Currently has breathing requirement that requires use of supplement oxygen during the day
- Now has pain or physical problem that may prevent deep breath or exhaling forcefully.

Spirometry only:

- Painful ear infection (ages 6-15 only)
- Eye surgery last 3 months
- Open chest surgery last 3 months
- Household member with tuberculosis
- Aneurysm
- Collapsed lung
- Detached retina (16-79 only)
- Stroke last 3 months (16-79 only)
- Heart attack last 3 months (16-79 only)
- Coughed up blood past month (16-79 only)

Bronchodilator exclusions:

- Currently pregnant (a positive urinary HCG test, or if unable to obtain, the self-report of pregnancy)

- Currently nursing a child.
- Has a elevated blood pressure, defined as > 180 mmHg systolic or > 110 mmHg diastolic for participants ages 17-79 years; ≥ 132 mmHg systolic or ≥ 92 mmHg diastolic for participants ages 12-16 years; and ≥ 124 mmHg systolic or ≥ 88 mmHg diastolic for participants ages 8-11 years.[11] Blood pressure measurements will not be performed in children less than 8 years of age.
- Has a resting pulse > 100 beats per minute if ages 16-79 years; or >102 if ages 12-15 or >104 if ages 8-11 or > 108 if ages 6-7 years.
- At the physician evaluation, has a history of a diagnosed major tachyarrhythmia (i.e. supraventricular tachycardia, ventricular tachycardia) and/or is taking a Class 1 Anti-arrhythmic from the designated list of medications (see below). Class 1 anti-arrhythmic medications will be screened by identifying MULTUM™Drug Class code 46 from the participants Household Interview prescription drug data. As a second check, the MEC physician will review all medication data reported by the participant as started after the time of the household interview as a cross check. Eligibility for bronchodilator testing in the presence of other diagnosed arrhythmias, or irregular pulse on examination will be assessed by the MEC physician history and examination. Untreated atrial fibrillation will be excluded, but controlled atrial fibrillation may be included based on physician evaluation. Sinus arrhythmia (a normal variant which is especially common in children and adolescents) will not exclude participants from bronchodilator testing.
- If the participant has an implanted automatic defibrillator or pacemaker (MEC Shared Exclusion Questions), this is an indication of a major arrhythmia, and they will be excluded from bronchodilator administration.
- If ages 6-15 years and has a history of congenital heart disease. Participants with a history of an asymptomatic, untreated heart murmur without evidence of heart disease will not be excluded.
- An adverse or allergic reaction to albuterol.
- Has epilepsy and is currently treated with anticonvulsant medication.
- Is taking a Monoamine Oxidase Inhibitor.
- If taking a tricyclic antidepressant, participants will be evaluated by the physician and excluded if they are over the age of 40, and have a history of heart disease, including , kidney or thyroid disease.
- If on physician evaluation, the participant is at risk for hypokalemia they are excluded. Risks for hypokalemia include diuretic therapy (hydrochlorothiazide, furosemide) without potassium supplementation or other concurrent medication that would raise potassium (ACE inhibitor, acetazolamide, etc.).
- If participants have inhaled a dose of a short acting beta-2 agonist bronchodilator or inhaled anti-cholinergic agent within the last 4 hours, or dose of a long acting beta-2 agonist bronchodilator in the last 12 hours will be excluded from post-bronchodilator testing, because they would be exceeding the FDA approved and recommended dosage for that specific medication. Participants currently taking beta-blocker medications will not be excluded from spirometry.

Justification for using vulnerable populations:

- Minors are included to obtain information on lung function and airway inflammation.
- Mentally impaired individuals will be included if they can follow instructions.

Risks:

Spirometry:

- Fatigue from multiple exhalations. In rare cases, a participant may hyperventilate and feel dizzy during the examination. Post-spirometric testing may include transient side effects: headache, dizziness/lightheadedness, cough, shortness of breath.

Bronchodilator:

- Transient side effects include rapid pulse, increased blood pressure, arrhythmia, nervousness, etc. but most are temporary.

Report of findings:

Spirometry
The lung function test was done with an Ohio Model 822/827 Spirometer. Your results below are an average of your lung function measurements.

	FVC (L)	**FEV1 (L)**	**FEV1/FVC%**	**Peakflow (L/sec)**	**FEF25-75% (L/sec)**
Your best values					
Predicted values					
Lower limits of normal					
Percent predicted					

Interpretation: Compared with other people of your age, sex, race/ethnicity and height, your breathing test results were <*outside or within*> normal limits.

Persons with bronchodilation and second spirometry (print only if it applies). Persons who have partial exams or poor quality in the second spirometry print:

Your lung function tests were not interpretable.

Otherwise, persons with completed exams:

Results after bronchodilation medicine (when used) will also be included.

ENO:

No report of findings

Vision

Public Health Objectives: Eye diseases cause suffering, disability and loss of productivity for millions of people in the United States. In economic terms, eye disease and blindness are estimated to cost the U.S. in excess of $22 billion each year. No high-quality, up-to-date information exists on the prevalence of visual impairment and the major causes of visual impairment in the general population. These data are needed in planning health services, in monitoring changes in disease prevalence, in research program planning, in developing and testing hypotheses about eye disease etiology.

Data collected over 20 years ago in the NHANES I (self-reported history questions and full vision examination with dilation) continue to be the only source of national prevalence data on eye disease and visual acuity impairment and there are no data on visual field impairment. Changes in disease definitions, population demographics, diagnostic capabilities, and treatments for eye diseases make it important to obtain new national data about eye disease. The absence of such data has forced researchers to use blindness registry data that are almost 25 years old. These studies select mostly white populations or non-nationally representative populations.

The ophthalmic data from NHANES will be used to: 1) measure the prevalence of visual acuity impairment in the U.S. population (visual acuity worse than 20/40), by cause; 2) measure the distribution of refractive error in the U.S. population; 3) evaluate screening strategies for visual impairment and eye disease; and 4) evaluate functional impairment related to vision.

Staff:

Health technician (MEC)

Protocol:

Methods:

Best corrective vision Visual acuity is measured with an autorefractor. The examinee puts his/her chin on the chin rest and focuses on a chart with numbers and letters in the autorefractor screen. Examinee is then asked to sequentially read the largest to smallest possible line on a built-in chart in the autorefractor. The technician isolates the smallest line read by the examinee with 1 error. With the examinee's eye focused on the line, the autorefractor quickly takes three repeated measurements, which is also known as objective refraction. These three auto-retinoscopy measurements, their average, and other measurements from the objective refraction are saved in a database. If required, these readings are further fine tuned to obtain best visual acuity based on objective refraction readings. Data from completed examinations are transferred to the ISIS and saved in a database.

Current Prescription The Lensmeter reads the current prescription of the eyeglass. This data is transferred to the autorefractor and later saved in the ISIS database to compare the current correction with the best corrective vision obtained from the auto-refractor.

Near visual acuity For the near visual acuity, older examinees are asked to read five lines of numbers and letters written on the near acuity card at the comfortable distance and this distance is measured and saved in the ISIS database.

Time Allotment: Depends on age and vision of sample person. Range 7-8 minutes. **Health**

Measures: The ophthalmic data from NHANES will be used to: 1) measure the prevalence of visual acuity impairment in the U.S. population (visual acuity worse than 20/40), by cause; 2) measure the distribution of refractive error in the U.S. population; 3) evaluate screening strategies for visual impairment and eye disease; and 4) evaluate functional impairment related to vision.

Eligibility: All sample persons aged 12+ years will have the refraction exam for the best corrective vision. Visual acuity assessment using the near card will be performed only on persons 50 years and over.

Exclusion Criteria:

Any evidence of injury (eye patch or bandage) or severe infection (i.e., purulent discharge with redness in eye) in both eyes.

Justification for using vulnerable populations:

- In recent years, myopia has been rapidly increasing in the U.S., especially among young adults and impaired vision is a major cause of motor vehicle accidents among older persons.
- Minors are included in this component because they are an important target population group. Visual acuity will be linked to other household interview and health component data and are used to monitor trends for impairment.
- Mentally impaired individuals will be tested if they can follow instructions.

Risks:

None. No mydriadic or anesthetic agents will be used

Report of Findings:

- MEC:

  Level 1: None
  Level 2: None
  Level 3: Visual acuity with recommendation

Text in MEC report is as follows:

We have done a quick check of your vision today. Our exam is not as precise as an eye exam done by an eye doctor. These values may differ from a vision exam you may have by an ophthalmologist, optometrist or optician

For vision 20/25 or better in both eyes with their current correction (either no correction, distance glasses and/or contact lenses):

Your distance vision is 20/__ in your right eye and 20/__ in your left eye with _____. This is a good level of vision. You should continue your usual schedule of periodic examinations by your eye doctor.

For vision worse than 20/25 in either eye with their current correction (either

no correction, distance glasses and/or contact lenses) :

Your distance vision is 20/__ in your right eye and 20/__ in your left eye with _____. This level of vision is not as good as most people's. If you were not already aware of this, you should see an eye doctor to see if he/she can improve your vision. Your eye doctor can also provide you with a full eye examination.