

Mobile Exam Center Components Descriptions

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

Arthritis

Public Health Objectives:

Among U.S. adults, there are three principal arthritis syndromes: Rheumatoid Arthritis, Osteoarthritis, and Spondyloarthritis, a form of spinal arthritis. Heretofore, considerable attention has been paid to Rheumatoid and Osteoarthritis, however a U.S. population based evaluation of Spondyloarthritis has not as yet been performed. This task becomes more urgent with the recent discovery that biologic chemotherapy can dramatically improve the course of the disease. It becomes a critical and urgent matter, therefore, to accurately define the U.S. population burden of the disease, to define its complete clinical spectrum from mild to severe cases, and its demographic variation in the U.S. The NHANES 2009-2010 Inflammatory Back Pain/Spondyloarthritis Component is designed to provide the first national-level data on these questions.

Low back pain is an extremely common condition in young adults, with significant socioeconomic impact. About 15% of the U.S. population has chronic low back pain, of whom approximately 14% (or 2% of the general population) will have inflammatory low back pain. Inflammatory back pain (IBP) is a hallmark of ankylosing spondylitis, whose over all population frequency in Europe approaches 1%. It has a similar economic impact as rheumatoid arthritis, with diminished survival over time, and significant functional impairment and disability.

Over time most patients with inflammatory back pain will demonstrate significant limitation in spinal mobility that can be demonstrated by body measurement tests. Further, HLA-B27, whose association with ankylosing spondylitis is well established, will be a marker of those with inflammatory back pain at greatest risk for developing limitation of spinal mobility over time. Spondyloarthritis is also associated with other major illnesses such as psoriasis and inflammatory bowel disease, and questions regarding these will be included in the main arthritis study protocol for 2009-2010 . The current proposal is to screen for the prevalence of inflammatory back pain in U.S. adults 20-69 years of age using a questionnaire for Inflammatory Back Pain history derived from questionnaires that have been extensively utilized by rheumatologists. Then, the prevalence of axial spondyloarthritis will be estimated by analyzing associations of the questionnaire data with the three measure of spinal mobility; and HLA-B27 testing.

Arthritis Component Protocol:

Age Eligibility:

Full sample of survey participants 20 to 69 years of age.

Exclusion Criteria:

There are no exclusions from the Arthritis component other than the standard NHANES exclusions for phlebotomy (blood drawing). Administration of the arthritis questionnaire and performing the 3 brief body measurements should not pose a risk to participants.

Arthritis Questionnaire:

This will be administered to participants in the NHANES household interview. A questionnaire to define a participant history of inflammatory back pain has been developed based on previous clinical instruments used in Rheumatology. It provides for data collection to define the presence of inflammatory back pain, principal contributing co-morbidities and risk factors. The instrument incorporates questions from previous NHANES back pain surveys where possible so as to facilitate prevalence trend studies over time.

MEC Examination:

Three previously validated physical body measurements will be obtained as an addition to the currently existing NHANES Mobile Examination Center (MEC) Examination Body Measures Component. These are simple body measures that can be readily obtained by the MEC Technicians. Total additional examination required is 3 minutes. All three measurements below are obtained to the nearest 0.1 cm.

1. Modified Schöber Test: This is a measure of lumbar spinal flexion. It is measured as the increase with forward flexion of a 10-centimeter segment marked on the patient's back with the inferior mark at the level of the posterior superior iliac spines. An increase in the measured distance of less than 5 centimeters with forward bending at the waist is regarded as abnormal in an adult.
2. Maximum Chest Wall Expansion: Chest expansion with inspiration is measured with a tape measure placed circumferentially around the chest wall at the fourth intercostal space. An increase of less than 2.5 centimeters with full inspiration is regarded as abnormal in an adult
3. The Occiput-to-Wall Distance: The participant stands with heels and buttocks touching the wall behind and with the knees straight. The patient is asked how far back he/she can get the head, still keeping the chin in the normal position. In the straight position, the distance between the posterior convexity of the occiput and the wall is measured to the nearest 0.1 centimeter. The better of 2 attempts is recorded. Any result other than zero is regarded as abnormal.

Laboratory Testing:

Laboratory testing for the NHANES Spondyloarthritis Component consists of HLA-B27 testing. HLA-B27 is a human histocompatibility locus marker which has been utilized as a standard clinical diagnostic test for many years to assist in the diagnosis of ankylosing spondylitis. In the symptomatic spinal arthritis patient population, it has an excellent sensitivity of (90%), a specificity of 90% as well as excellent positive likelihood ratio of 9 and a good posttest probability of 32%. The standard HLA B-27 test uses whole blood to assess for the presence of the human leukocyte antigen B27 by using an immunoassay or dot blot assay.

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 and 70+

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 (itches) 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 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. 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: Health technicians perform all of the NHANES body measurements using standardized examination methods and calibrated equipment. A recorder assists the examiner during the exam by assuring that proper positioning is maintained during the measurement process (particularly for young children). All of the body measurement data that are recorded during the examination are stored in the NHANES Integrated Survey Information System (ISIS) database.

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 survey participants are eligible for this component. The body measurement protocol varies 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: Weight is measured with a digital floor scale that has automated data capture and read-out capabilities. Weight measurements for infants and young children are made using the digital floor scale. First, the scale is set to zero (“tared”) with a parent or guardian standing on the scale. Next, the child is handed to the parent and the child’s weight is measured. All weight values are entered into the survey database electronically.

Stature (standing height): Stature is measured with a wall-mounted stadiometer that has automated data capture and read-out capabilities. Stature values are entered into the survey database electronically.

Recumbent Length: Length is measured with a measuring board called an infantometer that has automated data capture and read-out capabilities. Recumbent length values are values are entered into the survey database electronically.

Head circumference: A plastic head circumference measuring tape is used to measure head circumferences.

Limb lengths (upper arm and upper leg) and Circumference (mid-arm and waist) are measured with a steel measuring tape.

Skinfold Thickness Measurements: Subscapular and triceps skinfold measurements are made using skinfold calipers.

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

Bone Density Dual-energy X-ray Absorptiometry (DXA)

Public Health Objectives:

The dual-energy X-ray absorptiometry (DXA) component consists of 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 (cm²)
- Bone mineral density (gm/cm²)
- 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 (cm²)
- Bone mineral density (gm/cm²)

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.

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 from 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 ≥ 126 (if fasting 9 hrs) or ≥ 200 (if fasting <9 hrs).

Oral Health

Public Health Objectives: The purpose of this component is to assess the prevalence of oral conditions and diseases, such as edentulism, dental fluorosis, and periodontal disease. A set of periodontal questions will be assessed to determine the extent to which these questions provide an accurate basis for estimating prevalence of clinically-measured periodontitis in the US.

Over the past four decades, oral and dental health characteristics collected in national surveys supported by the Federal Government have been critical for monitoring health status, risk factors for disease, access to preventive and treatment services, and other health characteristics among the general population and special subpopulations. These studies include the National Health and Nutrition Examination Surveys (NHANES) and the National Health Interview Surveys (NHIS), as well as special surveys such as the Hispanic Health and Nutrition Examination Survey and the children's and adult surveys conducted by the National Institute of Dental and Craniofacial Research.

Oral and dental diseases affect many in the United States. Dental caries and tooth loss remain significant problems affecting the Nation's oral health. Although average dental caries rates for school-aged children have declined, approximately one-fifth of children age 6-11 years and two-fifths of children age 12-15 years have experienced dental caries in permanent teeth. Additionally, nearly 90% of adults in the United States have experienced caries. The 2009+ oral health components will meet a critical need to continue monitoring trends in oral health status. Unlike previous oral health exams conducted within NHANES, the new oral health exams will be conducted by registered dental hygienists (RDH) trained to administer the oral health screening assessments. The NHANES 2007-08 Basic Screening Exam for Oral Health (BSE) and Tooth Count will be continued. Additionally, an assessment for dental fluorosis will be performed on the upper six anterior permanent teeth. Finally, a full-mouth periodontal exam will be conducted, a first for any national health survey. This oral health exam will produce sufficient data to monitor 6 Healthy People 2010 oral health objectives (21.1 Dental caries experience; 21.2 Untreated dental decay; 21.3 No permanent tooth loss; 21.4 Complete tooth loss; 21.5 Periodontal Disease; and 21.8 Preventive dental sealant use).

Staff: Registered dental hygienists (RDHs)

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:

To maximize dental conditions of interest, two age groups will be selected for recruitment: children/adolescents ages 3-19 years, and adults ages 30 years and older.

Exclusion Criteria:

Participants identified as edentulous or have medical exclusions are not appointed to the oral health exam during their comprehensive examination at the MEC.

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:

- o **Minimal risk – including possible discomfort:**

These include possible discomfort, bleeding, and potential dislodging of already loose restorative material. There will be no exposure to radiation (no x-rays), hazardous material (no use of mercury) and no use of anesthetic agents.

Special precautions:

- o 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:

Tests and procedures conducted in this study are not considered diagnostic exams and are not a substitute for an evaluation by a health care professional. No clinical treatments or health interventions of any type are performed as part of this study. If a health problem is discovered during the course of the oral health exam, the RDH will offer to contact the examinee's personal healthcare provider or to recommend a dentist or clinic for follow-up care. If a participant is found to have a serious condition requiring immediate attention, the local emergency responders may be summoned or the participant will be advised to seek immediate medical treatment.

Each participant will receive some general results about the dental examination he/she received in this study. Each participant will receive a preliminary report of findings at the conclusion of the exam describing some general results including those from the dental examination. These

findings are also summarized in the Final Report sent to participants 12-16 weeks after their examination.

The report of findings is designed to list the specific recommendations for follow-up care based on subcomponent evaluation. There are four levels of referrals defined in the system as follows:

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

Recommendations for care levels are flagged for specific conditions. The dental examiner assigns an overall recommendation for the participant based on the care levels assigned to each subcomponent and his/her clinical judgment.

An examination recommendation for care level must be assigned to each and every participant by the examiner. If the participant does not have a condition that triggers a Level 1, Level 2, or Level 3 recommendation for any assessment, he/she will be flagged as a Level 4 recommendation for care referral. If the examiner finds any condition that warrants a different level of referral, he/she will override the system's referral.

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 \geq 210 and/or diastolic BP \geq 120; Pulse $>$ 140 bpm

Level 2: $140 <$ Systolic BP $<$ 210 and/or $90 \leq$ 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

| <i>Systolic</i> | <i>Diastolic</i> | <i>Statement</i> |
|-----------------|------------------|--|
| $<$ 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 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™ 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 an 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